THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM - OPENING DOORS TO NEW TECHNOLOGY

HEARING

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TUESDAY, NOVEMBER 8, 2005

HOUSE OF REPRESENTATIVES
COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON WORKFORCE, EMPOWERMENT
ANDGOVERNMENT PROGRAMS
Washington, DC

The Subcommittee met, pursuant to call, at 10:30 a.m., in Room 2360, Rayburn House Office Building, Hon. Marilyn Musgrave [Chairwoman of the Subcommittee] presiding.

Present: Representatives Musgrave, Westmoreland, and Lipinski. Chairwoman Musgrave. Good morning to all of you. This Committee will come to order.

Thank you all very much for being here today as we examine the Small Business Innovation Research Program, and we will refer to that as the SBIR from now on, for short. I also thank each one of our witnesses for taking the time to provide their testimony to our Subcommittee.

Established in 1982 via the Small Business Innovation Development Act, the SBIR program was established within the major federal research and development agencies. The intent of this effort was to increase government funding of small, high technology companies for the performance of R&D with commercial potential. Federal departments with and R&D budget of \$100 million or

Federal departments with and R&D budget of \$100 million or more are required to set aside 2.5 percent of this amount to finance SBIR activity. From its inception, over \$15.2 billion in awards have been made for more than 76,000 projects.

The Small Business Administration established broad policy and guidelines under which the current 12 individual federal agency departments operate their SBIR programs, and today we are going to focus on the agencies that we have invited to testify.

The SBIR program is an example of a highly successful federal initiative to encourage economic growth and innovation within the small business community by assisting in the funding of critical start-up and development stages of a company. Not only does it spur growth in the individual companies, the program stresses the importance of this Committee's and the entire federal government's commitment to expand and diversify research opportunities to small businesses, not just academic institutions and large businesses.

Small businesses represent the very core of the United States competitiveness. The post-World War II technological advantage we once enjoyed is certainly not as large as it once was. Diversifying federal research dollars through initiatives such as SBIR helps fos-

ter growth in our economy.

It is said that nobody holds the patent on good, new ideas. While that is true, it can be difficult for a small company with limited resources to take that idea and manufacture it into a new product or process. Programs like SBIR provide a bridge between product conception and marketability, a step of vital importance for innovative ideas to become reality.

The new technologies and discoveries that come out of this program go a long way toward keeping our competitive edge in the world marketplace. The SBIR program is the kind of public/private partnership that is essential to the continued growth of our econ-

I am eager to hear your testimony today, but before we begin that, I would like to yield to the distinguished gentleman from Illi-

nois, our ranking member, Mr. Lipinski.

[Chairman Musgrave's opening statement may be found in the

appendix.]

Mr. LIPINSKI. Thank you, Madam Chairman. I am glad to be here today to discuss the SBIR program and the role it plays in keeping our nation at the forefront of technological advancement. As a member of the Science Committee and also a former university professor, I am especially interested in this program, although don't take that last part to mean that I oppose the program, because I hear that it is not always the most popular program with universities.

In today's fast paced and highly competitive global marketplace, the United States continues to be a leader when it comes to technology. In no small part, the success is driven by the efforts of our nation's small businesses. Entrepreneurs continue to be dominant players in keeping the U.S. ahead, with small firms producing 55 percent of all new technological advances.

In order to ensure that our country keeps moving forward in science, engineering, and other high tech fields, we need to continue investing in small firms. The SBIR program is one of the leading tools that empowers small businesses to contribute to the

nation's technology sector.

SBIR enables entrepreneurs with bright, groundbreaking ideas to receive the valuable seed funding they need in order to start and grow their businesses. By opening a door for small firms to participate in federal research and development, this program is responsible for enabling thousands of small businesses to move their ideas

from laboratory to the marketplace.

The SBIR program has played a significant role in turning a wide variety of innovative dreams into reality, from quick-frozen foods to personal computers. By harnessing the imagination and spirit of small, high tech innovators, we strengthen our ability to meet national research priorities while laying the groundwork for the next generation of small technology firms in the U.S.

The SBIR program is not merely helpful, but is a critical program for spawning research and development in the early pre-commercial stages. Without the resources offered through SBIR, many small business will lack what they need to spur high tech innovation and development in order to move this nation forward for generations to come.

I look forward to hearing the testimony of today's witnesses, including ideas for improvement that will make the SBIR more equitable, efficient and productive. Thank you.

Chairwoman Musgrave. Thank you, Mr. Lipinski.

Our first witness is Calvin Jenkins from the Small Business Administration, and if the witnesses will observe the five-minute time limit, I would appreciate it. I will keep you honest on that.

Mr. Jenkins, welcome to the Committee. We look forward to your

testimony today.

STATEMENT OF CALVIN JENKINS, OFFICE OF GOVERNMENT CONTRACTS AND BUSINESS DEVELOPMENT, US SMALL **BUSINESS ADMINISTRATION**

Mr. Jenkins. Madam Chairman, Ranking Member, distinguished members of the Subcommittee, thank you for inviting the Small Business Administration here today to discuss the Small Business Innovation Research program.

I am Calvin Jenkins, Acting Associate Deputy Administrator for the Office of Government Contracts and Business Development at the SBA. I oversee the Office of Technology, which administers the

SBIR program.

The SBIR program, established in 1982, was designed to strengthen the role of innovative small business concerns and federally funded research and development, to utilize R&D as a base for technology innovation to meet agency needs, and to contribute to the growth and strength of the nation's economy.

The competitive grant program is operated by 11 agencies and has awarded more than \$16.9 billion to SBIR firms since its inception. Each federal agency with an extramural research or R&D budget in excess of \$100 million is required to set aside 2.5 percent of that budget for the SBIR program. The 11 participating agencies are: The USDA, Commerce, Defense, Education, Energy, HHS, Homeland Security, Transportation, EPA, NASA, and NSF.

The program is structured in three phases. Phase I awards provide up to \$100,000 to evaluate the feasibility and the scientific and technical merits of an idea. Phase II awards are funds up to \$750,000 for two years for the further development of the ideas proposed in Phase I. Phase III is the commercialization phase, and no SBIR funds are utilized. In Phase III, the awardee firms must either secure private sector investment to bring the innovation to market or obtain follow-on contracts with federal agencies to meet specific agency technology needs.

SBA's role in the SBIR program can be summed up in four main categories: Policy direction, program development; oversight of agency for compliance with policy direction; reporting program information, as required by statute; and outreach and marketing of

the program.

Each of the 11 participating agencies is responsible for administering and management of its SBIR program, including: Posting SBIR solicitations, receiving and evaluating proposals, selecting awardees, monitoring projects, submitting annual reports to the SBA containing complete records of their awards.

Each agency has its own technology needs consistent with its mission, as well as its own set of regulations and protocol. As a result, the SBIR program as a whole encompasses 11 very different

types of SBIR programs.

One important distinction is between agencies with clear technology needs, such as DoD and NASA, and agencies that do not procure technology themselves but, rather, have broader public interest missions, such as NSF or NIH. These programs are run in very different ways. Yet they all conform to the rules and framework we establish in the policy directives.

The number of awards have grown over time in proportion to the extramural R&D budget of the participating agencies. More than 82,000 awards have been made over the life of the program, totaling \$16.9 billion. Minorities, disadvantaged firms have received 10,074 awards, representing 12.1 percent of all SBIR awards.

Awards have been made to firms in all 50 states, Puerto Rico and the District of Columbia. Today, agencies evaluate over 30,000 proposals and make over 6,000 awards to about 3,000 small, high

tech companies each year.

Let us now address program performance. Past assumptions of commercialization rates of the SBIR program conducted by GAO, DoD and SBA have found that about 40 percent of Phase II SBIR

projects have resulted in commercial products.

We are currently implementing an online reporting system through an enhancement of our existing TechNet system to collect this information on an annual basis across all agencies. This should increase the reliability of the data and enable us to develop new measures of commercial success and critical program outcomes in the future.

I would also like to share a case study which demonstrates the benefits to small business and our technological growth. Sea Sweep, Inc., a Colorado firm, received a SBIR award from the Envi-

ronmental Protection Agency.

It utilized the award to develop and commercialize an innovative absorption called Sea Sweep that functions both on land and water to absorb spilled oil and chemicals. The absorption is made using a patented process that involves heating sawdust to a temperature at which the oil-like product renders it very attractive to oil but repellant to water. It absorbs the oil or chemical immediately upon contact, and will float indefinitely in water, preventing environmental damage to marine life and bird species.

In terms of commercial success, Sea Sweep is marketed in the United States, Europe, South America, Australia, New Zealand, Japan, Indonesia and the Persian Gulf. It has been recognized by R&D Magazine as one of the 100 most technologically significant

new products of the year.

Thank you for the opportunity to appear before you today, and I will be happy to answer any questions you may have.

[Mr. Jenkins' testimony may be found in the appendix.]

Chairwoman MUSGRAVE. Thank you, Mr. Jenkins. I am so sorry for the noise. We were like kids about to giggle in church, but that is no reflection on your testimony. We are trying to find the guy with the chain saw or whatever it is to shut him down. But my apologies, and if you want to give any of your testimony over—We don't know when it may start again, but if you want to venture in, we are happy to have you repeat any of it.

Mr. Jenkins. No, I think I am fine.

Chairwoman MUSGRAVE. Thank you. I am so sorry that happened to you.

Mr. Westmoreland said that is a reciprocating saw. So I have been corrected. Thank you.

Mr. Ramos, if you have the nerve, we would be interested to hear your testimony. Thank you for coming today.

STATEMENT OF FRANK RAMOS, OFFICE OF SMALL AND DIS-ADVANTAGED BUSINESS, OFFICE OF THE SECRETARY OF DEFENSE

Mr. RAMOS. Good morning, Chairman Musgrave and Congressman Lipinski and Mr. Westmoreland, and other members of the Committee. My name is Frank Ramos. I am the Director of the Office of Small and Disadvantaged Business for the Office of Secretary of Defense.

I want to thank you for the opportunity to appear before you and discuss the health and wellbeing of the SBIR program, and wanted to join my colleagues here today. We are working hard to ensure that the SBIR program is as effective as it can be.

The broad mission of the Department of Defense Small Business Innovation Research Program is to advance technology development for the warfighter and the nation. SBIR firms will enhance the defense industrial base and assure technology dominance by means of seeding technologies to provide material solutions to our warfighter.

The DoD SBIR program is a program of programs encompassing 10 military services and agencies. The DoD represents over 50 percent of the total federal SBIR budget, which exceeds \$2 billion. The DoD program has doubled in size from Fiscal Year 1999 to over \$1 billion.

In Fiscal Year 2004, 1,082 topics generated 15,681 proposals, 2,075 Phase I's; 1,173 Phase II contracts were awarded to 1,594 different firms from across the country. Again in Fiscal Year 2004, over 50 percent of the Phase I contracts were awarded to firms with fewer than 25 employees, and 30 percent to firms with fewer than 10 employees.

Many are start-up firms that bring their "out-of-the-garage" innovation to the Department. Again in Fiscal Year 2004, 39 percent of the SBIR Phase I award winners were first-time DoD contractors. Forty-eight percent had previously been awarded five or fewer Phase II contracts, and 19 percent were minority or women-owned firms.

The high water mark for SBIR success in the Department is bringing innovation, leading technology solutions, from small business to the warfighter. There is no way to measure the monetary value of a technology that saves a life in combat or contributes to the success on the battlefield.

We do, however, measure program output by tracking financial commercialization data on all Phase II contracts. We also track success stories that demonstrate impact on specific customers.

A vivid example is ceramic armor plates, which I've brought forward for you to examine, if you wish, which protect warfighters from assault and other small arms fire. Armor Works, Incorporated, of Phoenix, Arizona, has developed high-technology body armor plates for the Interceptor Body Armor System using the state of art ceramic materials stemming from a Navy SBIR contract that covered from 2000 to 2003 fiscal years, for vehicle armor and follow-on research and development.

The firm has supplied over 300,000 ceramic armor plates for use in personal, vehicular and aircraft applications that daily save

warfighter lives.

Another success story is the Phraselator—again we would like, if you wish, to demonstrate this later—a hand-held speech translation device developed by Marine Acoustics, a veteran owned small business firm based in Annapolis, Maryland.

This started from a DARPA SBIR effort. Following the terrorist attacks on 9-11 just seven months into the Phase II contract, DARPA requested acceleration of prototype Phraselator development.

Within weeks, 200 of the prototypes were delivered to military forces in Afghanistan. Over 350 are now deployed in Afghanistan and Iraq, and were used exclusively in the tsunami relief efforts. Thousands are in use by the military around the world, with a large potential commercial market for law enforcement and medical applications.

A third success story is a portable very high bandwidth satellite communications antenna developed by Systems Technology Group of SRS Technologies, Huntsville, Alabama, through an SBIR Phase II contract with the Air Force Research Laboratory and with fund-

ing from the Office of the Secretary of Defense.

First responders used the antenna system in Biloxi, Mississippi, to provide communications in the destructive wake of Hurricane Katrina. The antenna systems enabled them to establish a law enforcement command post and a refugee information center. So impressive were the antenna's capabilities that FEMA and the Red Cross are interested in the technology.

In summary, again I thank you, Madam Chairman, for the opportunity to testify before you on the SBIR program. I hope my testimony has provided you with a summary understanding of the DoD SBIR program. Additionally, I hope this has given you a sense of its importance to our notion's worfighter.

of its importance to our nation's warfighter.

I look forward to continuing to work with you and other members of the Congress, and I stand ready to answer any questions. Thank you so much.

[Mr. Ramos' testimony may be found in the appendix.]

Chairwoman Musgrave. Thank you, Mr. Ramos, very much.

Dr. James Decker is with us from the U.S. Department of Energy. Welcome.

STATEMENT OF JAMES DECKER, OFFICE OF SCIENCE, U.S. DEPARTMENT OF ENERGY

Mr. Decker. Thank you. Madam Chairman, members of the Subcommittee, thank you for inviting me to speak today about the SBIR program at the Department of Energy.

I am the principal Deputy Director of the Office of Science. The Office of Science manages the SBIR program for the Department

and has done so since the SBIR program started in 1982.

In addition to the Office of Science, six other DOE R&D programs participate in the SBIR program: Fossil Energy; Energy Efficiency and Renewable Energy; Nuclear Energy; Environmental Management; Defense Nuclear Nonproliferation; and Electricity Delivery and Energy Reliability.

The DOE SBIR program currently provides over \$100 million each year to small businesses to help entrepreneurs take their ideas from conception to reality. The Department has, since the program's inception, made 4,123 Phase I awards and 1,677 Phase

II awards, with a total value of about \$1.4 billion.

Of the Phase I awards, about 12 percent are awarded annually to socially and economically disadvantaged small businesses, and about a third are first-time awardees with DOE.

In return, these companies have earned more than \$3 billion in sales and additional development funding, created jobs, and helped

the nation capitalize on its substantial investment in R&D.

The Department manages the SBIR program with nearly the same processes that it uses in general for R&D programs. The Department issues an annual solicitation for the SBIR program. It typically contains approximately 50 topics, including renewal engasification, sources, coal combustion nanotechnology, biological solutions for producing fuels, advanced technologies for nuclear energy, and high performance computing, just to name a few.

Applications are first reviewed by the technical managers to ensure the proposals meet the notice requirements. Grant applications then go through a peer review process by outside, independent, scientific and technical experts. Based on the results of these external reviews, each technical program makes their selections, and the final decisions are made by the DOE SBIR program manager based on these recommendations.

One aspect of our SBIR program that is different from our standard management of R&D programs is our commercialization assistance. DOE was the first agency to offer commercialization assist-

ance to awardees, beginning in 1990.

A large majority of SBIR awardees have excellent skills in science and engineering research, but lack experience in product development, financing, business growth, raising venture capital, and marketing. So one of the services provided to Phase II awardees for the last 15 years is the Commercialization Opportunity Forum Program.

This program is conducted by Dawnbreaker, a private organization under contract to the Department. In workshops and one-onone sessions, Dawnbreaker works with small businesses over a pe-

riod of eight months to develop and refine a business plan.

During a two-day Opportunity Forum, Dawnbreaker brings these small businesses together with respective entrepreneurs, investors, and potential strategic allies. Other commercialization services offered through the Department's SBIR program help small businesses to develop roadmaps for commercialization and to assess potential applications for their technologies.

We have worked diligently to make this program a success, and we believe it is. The quality of the research selected for awards has remained very high. We are pleased that at least 25 of our projects have received R&D 100 awards from Research and Development Magazine that selects the 100 most significant technical products

each year.

Some examples of the technologies that have been successfully commercialized as a result of the Department's SBIR program include: Photovoltaic power systems for more cost effective solar power generation; catalytic combusters that reduce pollution from gas turbine engines; web-based search engine software that optimizes desired search results from multiple database Internet searching; automated blood purifiers for faster DNA purification and genome analysis; shock resistant, temperature tolerant ceramic components for an improved energy efficiency of diesel engines; and fuel cell technologies that improve efficiency.

In conclusion, I believe that the Department's SBIR program has successfully met the purposes of the program established in the Small Business Innovation Development Act. In addition to the benefits to the participants and to the nation from commercialization of new products resulting from the SBIR program, the Department of Energy has benefitted from small business participation in its R&D programs, and small business continues to contribute in-

novative solutions to difficult technical problems.

The Department of Energy will certainly continue to support SBIR, and continue to look to small business innovators and entrepreneurs to help keep our nation at the cutting edge of science and global competitiveness.

Again, thank you, Madam Chairman, for inviting me to testify today, and I would be happy to answer any questions you or mem-

bers may have.

[Dr. Decker's testimony may be found in the appendix.] Chairwoman MUSGRAVE. I appreciate your testimony.

We have Dr. Norka Ruiz Bravo now from the National Institutes of Health. Welcome to the Committee.

STATEMENT OF DR. NORKA RUIZ BRAVO, NATIONAL INSTITUTES OF HEALTH

Dr. Ruiz Bravo. Good morning, Madam Chairwoman and members of the Committee. I am Dr. Norka Ruiz Bravo, Deputy Director for Extramural Research at the National Institutes of Health.

The NIH is a component of the Department of Health and Human Services, and it is the principal health research agency of the federal government.

Our mission is the conduct of biomedical, behavioral and clinical research to improve the health of the American people, and I am pleased to appear before you today to testify about the NIH's SBIR program and the role that it plays in opening new doors to new technologies.

Specifically, I am going to focus on two areas, first the role that SBIR plays in the NIH research agenda and, second, several benefits of the program within our agency and across the country.

The SBIR program is fully integrated within the scientific programs and goals of the NIH by contributing to the translation of scientific findings into tangible products and services that benefit public health. Across the NIH, there are 24 Institutes and Centers with SBIR programs, each of which has well defined scientific research priorities.

Through a competitive phased award system, the SBIR program supports a wide array of innovative biomedical and public health projects that are designed to encourage commercialization of promising technologies. I would like to highlight just two of the many technological advances that I feel exemplify the kind of SBIR research that NIH supports.

The first is funded by the National Heart, Lung, and Blood Institute, AVANT Immunotherapeutics. This company used the SBIR program to demonstrate the feasibility and then advance a revolutionary vaccine that is designed to enhance the clinical management of atherosclerosis. That is the hardening and narrowing of arteries.

Second, the National Eye Institute funded IntraLase Corporation through the SBIR program to develop a safer, more precise laser for creating the corneal flap. Many of us have heard about LASIK. This relates to that. The fentosecond laser pulse virtually eliminates the severe sight threatening complications that are often seen or sometimes seen with the microkeratome.

To grow this long line of successes, the NIH has initiated several steps to increase the efficiency and effectiveness of our SBIR program. These enhancements, such as flexibility in time and dollars and the Fast Track mechanism as well as others described in my written testimony arise, from and respond to many of the needs of the small business research community. Those needs are varied, and the challenges are great in trying to accommodate multiple industries, different technology sectors, and diverse product outcomes.

The journey through the innovation pipeline for many biomedical products is a long and complicated one. Progress in biomedical research cannot always be considered a simple linear process, though the phased structure of the SBIR program construes it as such.

For the majority of the companies that we support whose major business focus is biotechnology, pharmaceutical—for example, drug discovery and drug development—and diagnostic, the phased SBIR program process is a cyclical process that is met with unique challenges. Phase I plus Phase II does not automatically translate to Phase III commercialization.

Additional SBIR funding is often needed to pursue lines of feasibility research related to the development of products to benefit human health.

In conclusion, the NIH is very pleased with its involvement in the SBIR program, and believes that flexibility is critical to the continued success of the program. This concludes my statement today. I would be happy to answer any questions from the Committee.

[Dr. Ruiz Bravo's testimony may be found in the appendix.]

Chairwoman Musgrave. Thank you very much.

We have Dr. Colien Hefferan next. Thank you for coming from the Department of Agriculture. My district back home has 75 percent of the population along the front range, and then 25 percent over this vast rural area where the whole economy is based on agriculture. So I am happy to hear your remarks today.

STATEMENT OF COLIEN HEFFERAN, COOPERATIVE STATE RESEARCH EDUCATION AND EXTENSION SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Ms. Hefferan. Thank you. Well, good morning, Madam Chairman, and Congressman Lipinski. I am Colien Hefferan, the Administrator of the Cooperative State Research Education and Extension Service at the U.S. Department of Agriculture, the agency charged with administering the SBIR program on behalf of USDA.

I would like to give you a brief overview of the program, the way we administer the funds, and the focus areas that we look to.

Within USDA we have eight agencies which provide support for the program. Eighty percent of the funding comes from my organization, 12.5 from the Agricultural Research Service, and five percent from the Forest Service, with smaller amounts coming from each of a series of other agencies.

As with other agencies, we provide two types of awards. We provide up to \$80,000 for eight months for Phase I feasibility studies, and for Phase II research and development grants, we provide up to \$300,000 for 24 months. Approximately 90 Phase I feasibility grants and 35 to 40 Phase II development grants are awarded annually.

The successful completion of a Phase I study is a prerequisite to receipt of a Phase II grant. Of the applications that we receive, 15 to 17 percent of the Phase I and 50 to 60 percent of the Phase II

applications have been funded each year.

Our program addresses 12 research topics which cover the range of issues addressed by the U.S. Department of Agriculture, including enhancing economic opportunities for producers, increasing the quality of life in rural America, enhancing protection and safety of the nation's food supply, improving the nation's nutrition and health, and protecting and enhancing the natural resource base.

Within these topics, over the years we have added topics, including this year for the first time a program focused on small and midsize farms.

Proposals are evaluated through a confidential peer review system similar to that used by our National Research Initiative, which is the flagship competitive research program at USDA and which is modeled after the National Science Foundation peer review system. Our panels meet in Washington, and the most meritorious applications are recommended for funding.

Also, when there are areas of specific expertise that we need to

address, we use ad hoc reviewers from all over the world.

A very important aspect of our SBIR program is post-award management. Most of the effort is directed toward Phase II projects

that have demonstrated technical feasibility in their first phase. A commercialization assistance program is offered to new Phase II winners in which they work with a contractor who helps identify commercialization partners and markets, which are often the most critical issue, and new business opportunities.

In addition, our program leaders for the SBIR program conduct

many site visits and work very closely with our recipients.

The successful commercialization often takes several years beyond the actual award of programs and projects by USDA, but surveys of our past Phase II winners indicate that about 50 percent of those projects ultimately realize success in the form of commercialization and sales.

I would like to briefly mention just one or two examples of successful SBIR projects. The first is Embrex from Research Triangle Park in North Carolina. Chickens used to be vaccinated on the first day after hatching for a variety of diseases, and you can imagine, that is not an easy job. USDA scientists showed it was possible to vaccinate chickens by injecting the vaccine directly into the egg three days prior to hatching.

three days prior to hatching.

To make this "in ova" vaccination approach, Embrex received an SBIR support to develop an automatic egg injection machine. Their technology is capable of vaccinating 30,000 eggs per hour, and they now vaccinate over 90 percent of the 9 billion broiler chickens raised in this country every year. They are also vaccinating chicken

eggs in more than 30 foreign countries.

This technique has been shown to be effective with viral diseases and, should we be successful in developing, for example, a vaccine that can address avian influenza, this technology is available and could be used for that purpose.

We have a number of other examples of success, including the Nitrate Elimination Company in Lake Linden in Michigan's Upper Peninsula. This project focuses on nitrogen fertilizer leaching from

soil into water supplies.

Traditionally, nitrogen in those areas has been measured by using cadmium, but cadmium is very toxic and poses a threat to human health. So the testing for nitrogen was a toxic process in itself. The Nitrate Elimination Company has produced a very sensitive test kit for nitrate that is based on the activity of an enzyme nitrate reductase and, therefore, reduces the cadmium that is used in this process.

We have many other examples of success from the 1600 projects that we have supported since 1982 when the program began, and we will be very pleased to provide those and other examples to you.

Thank you for this opportunity.

[Dr. Hefferan's testimony may be found in the appendix.] Chairwoman MUSGRAVE. Thank you for your testimony.

We now have Dr. Joseph Hennessey from the National Science Foundation. We look forward to hearing from you.

STATEMENT OF JOSEPH HENNESSEY, NATIONAL SCIENCE FOUNDATION

Dr. HENNESSEY. Thank you, Madam Chairman and Mr. Lipinski. I am Jose Hennessey. I am Senior Advisory in the NSF SBIR program.

This morning I would like to share some information with you on our Phase IIB program. The details of that are summarized on page 3 of our written testimony. To do that, I want to tell you a story, and I have entitled the story "Save the Plant."

It turns our last week I was talking to Tom Knight, who is one of our Phase IIB awardees. Just a little background: Tom is the CEO of a small company in Georgia called Invistics, and before he started Invistics Tom was a manufacturing manager in a number of large companies. While he was doing that, he was very disappointed with the quality of the software that was available to reduce cycle time and to improve manufacturing performance.

Tom started his company and got a Phase I and subsequently got a Phase II from NSF, and while he was doing that, he also partnered with professors from MIT and Georgia Tech to develop with him the algorithms that were required for this software.

During the Phase II, he also secured investments from angels as well as local venture capitalists, and that really served as the matching funds for securing a Phase IIB from the National Science Foundation.

As they developed this web-based modules for planning, scheduling, delivery and inventory, Invistics also began to consult with a number of major potential customers. Within about three years, Invistics systems have been adapted by a number of those companies.

One of Tom's customers is Bristol-Myers Squibb. I am sure you recognize them, a major pharmaceutical manufacturer. They had a plant in Evansville, Indiana, that was scheduled to be closed, and basically as a last ditch effort, they implemented the lean manufacturing techniques that were supported by Tom's software, along with a team management concept.

In 2005, the same plant received the Team of the Year Award from Pharmaceutical Manufacturing Magazines, and is now recognized as one of the highest performing pharmaceutical plants in

Why did I select Invistics to share with you this morning? We are doing this, because we believe they exemplify what we are looking for in successful small businesses. They understood what their customers needed. They used the SBIR funds to carry out the ap-

propriate research.

While they were carrying out this research, they attracted appropriate investments during Phase II. They recognized they needed that to move on toward commercialization. They leveraged academic research. They also learned how to sell, to market and sell, systems to large companies, and particularly in this case, these systems had to be compatible with many of the systems that were already in place in these companies.

What we are looking for is we would like to see more of our small business clients be more like Invistics. NSF is trying to expand significantly what we call our awards management and mentorship activities with these small businesses. We see many small companies who have great technologies. However, they are really lacking in the business skills necessary for successful commercialization.

Madam Chair, that concludes my testimony, but I will be happy

to answer any questions.

[Dr. Hennessey's testimony may be found in the appendix.] Chairwoman Musgrave. Thank you very much to all of you. Very interesting testimony.

Mr. Ramos, I am going to start with you. You've got a couple of things that you brought. Could you tell us about them, please?

Mr. Ramos. Sure. i would like to start with the Phraselator. This company—and one of the gentlemen that's in the room here, a former Navy Seal, is one of the principals in the company. I am not sure if you want to see a demonstration or you just want to speak to it.

Chairwoman Musgrave. If it is all right with Mr. Lipinski, I would love to see a demonstration.

Mr. Lipinski. I actually was going to say that I had heard about this on the news and was going to ask you, Mr. Ramos, for a demonstration.

Mr. Ramos. Here is the owner of the company. He is better at doing this.

Chairwoman Musgrave. All right. Imagine that. He brought his

own. Okav.

Mr. Ramos. While he is going up there, I want to mention, because, Ms. Chairman, this is one of our veteran-owned firms. I know you had a panel before on the veteran-owned businesses. This exemplifies what Department of Defense is doing using our own to develop products for the warfighter.

Chairwoman Musgrave. Very good.

Mr. Sarich. What this did is I spoke to it, and it matched my input speech with a recorded output translation. So when we first started on this, we ran it on a notebook PC, and we needed to find a way to get it down to something that the warfighters could use, and through the SBIR program—You know, I didn't even know it existed. I was brand new to it, but we were able to come up with

It has multiple languages. That was Iraqi. If I wanted to switch to another language: Switch to Italian. This is a computer translator.

So it works for anybody. It works for my voice, but it would also work for most anybody in the room after a couple of tries so you could get used to it. We have been developing this now—The first working prototype had worked—was ready in September of 2001, and then shortly thereafter I found myself in Afghanistan the first time in 2002.

From that time, we have been refining and iterating on it, and I just have to tell you, I'm just—I am a total believer in this program, you know.

I would be glad to answer any questions you might have.

Chairwoman Musgrave. Well, very interesting demonstration. Mr. Lipinski, did you have any question?

Mr. LIPINSKI. What languages can you do? Mr. SARICH. Well, right now, because it is—we could have multiple languages, in fact, for this particular set of phrases we have you take a look at it—probably about 15 different translations, and we have the toolkit so that we can add new translations.

We can also have the warfighter. We have a toolkit and, in fact, we have been training the warfighters to be able to add their own content with their own linguists. They have their own linguists or we build the content for them.

As I said, we recently have—Just out at Camp Pendleton where they are actually institutionalizing this in their training at the 1st Marine Division, as the Marines get ready to go overseas there, a certain portion were trained in how to use this device.

We've got about 5,000 or approaching 5,000 of the Phraselators

out in the field now.

Chairwoman MUSGRAVE. Does it have a battery in it, and what

is the life of the battery?

Mr. SARICH. My background is—I have a military background and engineering background, and from my SEAL background one of the things I realize is that batteries are big, you know, because we've got so many batteries. So what we did is we have a custom lithium polymer battery, which is good for about 20 hours-plus of normal use, which in its sleep mode is good for weeks or better.

Also, it will take four AA batteries, because, you know, warfighters don't always have a place to charge the battery, but

usually they can find AA's.

Chairwoman MUSGRAVE. That's what I was wondering. What is your name again, please?

Mr. SARICH. My first name is Ace, and last name is Sarich, S-

a-r-i-c-h.

Chairwoman Musgrave. Thank you so much, Mr. Sarich. Did you have anything else, Mr. Lipinski? Thank you very much.

Mr. LIPINSKI. No. Thank you very much.

Mr. Sarich. Thank you.

Chairwoman MUSGRAVE. All right. The second thing that you brought with you, the armor? Could we have your name, sir? You can come up to a microphone.

Mr. CERVANTES. Charles Cervantes. I am Special Assistant to the

Mr. RAMOS. This device, again, I'm sure, is saving numerous lives. What is really impressive about it—and this goes to the credit for the young men and women that are out there in the field of harm—is the weight. These weigh about six pounds, and they carry anywhere from five around their body, and they carry that in the heat and the other equipment that they carry.

So if anybody was to criticize those young men and women, I'm sure I am going to stand up and say try one of these on and carry it around all day.

Chairwoman Musgrave. Tell us how it withstands, Mr. Cervantes or Mr. Ramos, whichever.

Mr. RAMOS. I'm sorry? What was the question?

Chairwoman MUSGRAVE. You have told us about the weight. How is it made?

Mr. RAMOS. Well, it is a ceramic material that has been developed through the SBIR program, as I mentioned earlier, and it is inserted into panels like a vest that they wear around their body. You have probably seen them on television, and they protect them in the vital parts of their body, particularly in the chest area.

So that is the intent of this. A story is: My nephew was in Vietnam, and they used to steal manhole covers and put them on the bottom of the helicopter. These are the type of devices now that are

replacing the manhole covers to protect them, which is a state of the art, again.

Chairwoman Musgrave. Is it put on equipment as well as soldiers?

Mr. RAMOS. Yes. As I mentioned, it is put on the—Personnel protection is put on vehicles and put on aircraft as well.

Chairwoman Musgrave. How is it attached to a vehicle?

Mr. RAMOS. Well, I don't know in detail, but what I understand is that they are put into the panels, and they are, if you will, bolted onto the side of the vehicle so that they are given some protection, and they are also laid in the bottom of the vehicle so that, in case there is some concussion, it protects them.

Particularly in the aircraft, very possibly like in the helicopter where my nephew was on, they get fire from underneath, and it penetrates them where they are sitting. So this then would protect them in some form.

Chairwoman MUSGRAVE. Mr. Lipinski?

Mr. LIPINSKI. For questions, questions for Mr. Ramos? Chairwoman MUSGRAVE. Whichever you would like.

Mr. Lipinski. Okay. Thank you very much, Mr. Ramos. I don't have any other questions on that, but both of those two examples show just great examples of American ingenuity and show what we can do, what small businesses can do, and make great technological improvements, and here very much help our military and our men and women in serving to protect us right now.

My main question for the panel goes to what is probably the biggest controversy right now or discussion at least in regard to SBIR.

That is the limit on venture capital.

If 51 percent or more venture capital, then you cannot apply for SBIR program, and this has come out of a Small Business Administration ruling. I am just wondering—and I am not taking a position here. What I am interested in is information.

I am not sure how much Mr. Jenkins can say about this right now, but I am interested to hear from you, Mr. Jenkins, and everyone else about their department or agency what impact you think that that limit had, and is it—Well, you can put in it whether or not you think it is a good impact or not, but I am just wondering what impact you think that does have on the SBIR program and how it accomplishes its goals in your particular department or agency.

Mr. Jenkins. Yes, sir. As you mentioned, as a result of Office of Hearings and Appeals findings, SBA clarified its rules regarding the ownership issue, and our rule has always stated that 51 per-

cent must be owned by an individual.

We have heard from both sides in terms of whether or not we should allow for venture capital to participate. We have also heard from small businesses that feel that they would be competing unfairly. So I think it is important for SBA to continue to look at the comments that we have received and actually try to weigh them and come to some conclusion at this point, but we have not yet made any kind of decision to change our rules at this point.

Mr. LIPINSKI. Mr. Ramos?

Mr. RAMOS. At this point, I think we want to defer to the SBA and see what policy guidelines come out. There are, obviously,

some pros and cons on it. There's been some discussions in the past.

I have a book here on the National Research Council that was addressed—that issue was addressed, and there are a lot of variances in terms of where this plays into, particularly in the topic area of interest with respect to either angel investment or venture capital. But at this time, I just don't think I can address it, because we are looking to the SBA to give us some guidelines on that.

Mr. LIPINSKI. Is there anyone who will venture an opinion on

what impact you think that it has? Dr. Bravo?

Dr. Ruiz Bravo. I would be happy to. For us at the NIH, if you recall the SBA issued a new rule in 2005. It became effective in 2005, and that opened the door to venture capital companies, majority ownership by a single venture capital company. We think that is terrific.

It opened the door some, but perhaps not as much as would be beneficial to the National Institutes of Health. For us, particularly for companies that deal with drug development, drug discovery, therapeutics, for those kinds of companies less than one percent of those innovative research projects actually reach the marketplace, and they have a number of characteristics.

For example, they have very high intensive capital needs. They require an unusually long development time. They are exceptionally high in burn rate of investment funds. In other words, they go through money very quickly. Sometimes it takes hundreds of millions of dollars to get a drug to market, and they require significant investment by the venture capital companies, and they require multiple venture capital financing.

So for those kinds of companies, while the SBA's rule opened the door somewhat, it didn't open it sufficiently to allow us to reach some of those kinds of companies; and in fact, we have had some companies that we thought we were going to be able to fund that have applied for grants, and we have had to turn them down. I can give you one or two examples of that.

Mr. LIPINSKI. Thank you. Anyone else want to—I am not trying to paint anyone into a corner. It is not a trick question. I was trying to get information on how you see this having an impact.

Mr. Decker. At the Department of Energy, we don't think that the present guidelines has had a adverse impact on our program. I think it probably does depend a lot on the type of business that the company is in and what they are trying to do as to whether or not this is a significant issue. We just don't see it with the companies we deal with.

Mr. LIPINSKI. Okay. Any others?

Ms. HEFFERAN. Well, I would add that at USDA we have had relatively few cases where this has been an issue thus far, although, certainly, there is a growing Ag biotech sector. So it could have an effect similar to NIH, but at this point it has not been a substantial issue for us.

Mr. LIPINSKI. Thank you.

Mr. HENNESSEY. It hasn't really been an issue at NSF, even with our Phase IIB program. So we haven't really taken a position. However, we certainly can support the position that NIH has taken on it, but it hasn't been a handicap for us in managing our pro-

Mr. LIPINSKI. Thank you. Further question?

Chairwoman Musgrave. Certainly.

Mr. LIPINSKI. I had another question arising out of the testimony. I know that Dr. Decker talked about the Department of Energy was the first to aid in commercialization, and Dr. Hennessey talked about what NSF does with the Phase IIB.

I was wondering if other departments and agencies—what they

do in regard to helping with commercialization. Dr. Bravo? Dr. Ruiz Bravo. NIH does have a commercialization assistance program where small agencies are basically taught about how to get through what is called the "valley of death," which is the place of getting through from having a great idea and the beginning of a product out to the product.

Mr. Lipinski. Thank you. Mr. Ramos—Go ahead, Dr. Hennessey. Mr. HENNESSEY. NSF has a program that we call our Phase I commercialization planning assistance program, which works with all the Phase I grantees to help them develop a commercialization plan as part of their Phase I submission. That has been very successful in improving the quality of the Phase II proposals.

We are evaluating now alternatives and how we can expand that to help-in addition to our Phase IIB program, how we can expand

that to help our active Phase II grantees.

Mr. LIPINSKI. Thank you. I always make it a point, whenever anyone from NSF is testifying before a Committee that I am on, to say I am always happy to see someone from the NSF, because I have applied for one NSF grant in my life, and I received it. So it's always good. Dr. Hefferan.

Ms. Hefferan. In the case of the Department of Agriculture, we limit the technical assistance to the Phase II awardees, and it is done through contracts with firms that provide education and training, particularly for this transition from the development of the product to the development of something you can sell, and that

is limited to a contract valued at \$4,000 per recipient.

I think there are a lot of other avenues that could be developed to help with technical assistance. At USDA, of course, we have the Cooperative Extension Program which can help with commercialization and business development. NIST has a manufacturing extension program, and obviously, SBA and other programs have technical assistance.

So we try to encourage our recipients to use a wide range of resources, many of which are low cost or free for small businesses, but the formal program is limited to the Phase II awardees.

Mr. Lipinski. Thank you. Mr. Ramos?

Mr. RAMOS. I am one to use empirical data to make determinations, and we have two studies that are ongoing right now, one from the National—I've forgotten the name here—the National Academy of Science, and we also have the RAND.

This has been an interest of both the House and Senate side in small business, and before we come forward with any conclusions, we better serve to the Congress if we get that empirical data to examine where these solutions may be applied.

Mr. LIPINSKI. Thank you. Thank you very much.

Chairwoman MUSGRAVE. I just wonder what kind of interagency information sharing you all do. Anyone want to comment on that?

Mr. Jenkins. Well, in terms of the SBA, the data is clearly important for us in order to track the success of the program. I think, as we move forward and make some modifications to our data collection system, we will be able to continue to show the success of the program, in all phases, but certainly through commercialization.

So we collect data from each of the agencies to help us with that, and show the benefits of the program.

Mr. RAMOS. What we undertook this last year was a joint Department of Defense Phase II forum. We invited other agencies to participate, and for the first time we focused on Phase II and beyond.

That seems to be a forum where we can push the program a little more effectively than we have in the past, and we plan to have another iteration of that forum again with our sister organizations.

Chairwoman MUSGRAVE. Very good. It seems that the east and west coasts have more award winners than anywhere else. Does anyone have a comment on that, why that might be the case?

Mr. RAMOS. I am from the west. They are smarter.

Mr. LIPINSKI. I would take offense to that.

Mr. RAMOS. I just want to make reference to Congressman Tom Davis in one of the periodicals, that he was a guest speaker at one of these forums, and I think there is a circle trend in terms of where seats of technology sit. They seem to be principally in the Boston, Massachusetts, quarter and in California.

Why that is, I think that is for any of the academics to speculate, but some people say that is the innovative environment that exists in those areas. Again, that is very subjective, but that seems to be a pattern

a pattern.

Chairwoman Musgrave. Are there any particular industries that you all see that are getting an increase in awards? No trend there? All right.

Is there anything that you would suggest about the way the program is administered? Would you like to see any changes that would cause it to improve? Dr. Bravo?

Dr. Ruiz Bravo. Î think I have already mentioned the kinds of things, the flexibility around the eligibility, that would help NIH fund the kinds of applications that we need to fund.

Chairwoman Musgrave. Anyone else like to comment on any changes they would like to see?

Very interesting testimony today. Dr. Hennessey?

Mr. Hennessey. We noted in our testimony that the area of discretionary funding to help with technical assistance, and for a lot of us technical assistance is really defined as helping them understand the principles of commercialization.

I think a number of us believe that that would enhance our capability to do more mentoring, counseling, and try to address some of these issues that I mentioned before, a lot of great technologies, but how they get from technology to the marketplace—there is a huge gap of knowledge there in many of these companies.

Mr. Decker. We, certainly, at Department of Energy support that position. We think that is a critically important piece for the success of this program.

Chairwoman MUSGRAVE. Thank you. Well, thank all of you. I know Trent Lott talks about herding cats, but then we heard about vaccinating eggs today, and I found that very intriguing, trying to imagine vaccinating a chick. So what an innovation.

Good testimony today, and thank you also to you two gentlemen

who assisted with demonstrating those things for us.

This Committee is adjourned, and again thank you for coming.

[Whereupon, at 11:07 a.m., the Subcommittee was adjourned.]

OPENING STATEMENT

- · Good Morning.
- Thank you all for being here today as we examine the Small Business Innovative Research Program, the SBIR Program for short.
- I also thank each of our witnesses for taking the time to provide their testimony to this Subcommittee.
- Established in 1982 via the Small Business Innovation Development Act, the SBIR program was established within the major federal research and development (R&D) agencies.
- The intent of this effort was to increase government funding of small, high technology companies for the performance of R&D with commercial potential.
- Federal departments with an R&D budget of \$100 million or more are required to set aside 2.5 percent of this amount to finance SBIR activity.
- From its inception, over \$15.2 billion in awards have been made for more than 76,000 projects.
- The Small Business Administration established broad policy and guidelines under which the current 12 individual Federal agency departments operate their SBIR programs, and today, we're going to focus on the agencies we have invited to testify.
- The SBIR program is an example of a highly successful Federal initiative to
 encourage economic growth and innovation within the small business
 community by assisting in the funding of critical startup and development
 stages of a company.
- Not only does it spur growth in individual companies, the program stresses the importance of this Committee's and the entire Federal government's

commitment to expand and diversify research opportunities to small business, not just academic institutions and large businesses.

- Small Businesses represent the very core of United States competitiveness.
 The post-World War II technological advantage we once enjoyed is certainly not as large as it once was. Diversifying federal research dollars through initiatives such as SBIR helps foster growth in our economy.
- It is said that nobody has a patent on good new ideas.
- While that is true, it can be difficult for a small company, with limited resources, to take that idea and manufacture it into a new product or process.
- Programs like SBIR provide a bridge between product conception and marketability—a step of vital importance for innovative ideas to become reality.
- The new technologies and discoveries that come out of this program go a long way toward keeping our competitive edge in the world marketplace.
- The SBIR program is the kind of public-private partnership that is essential to the continued growth of our economy.
- I am very eager to hear today's testimony, but before we begin, I would like
 to yield to the distinguished gentleman from Illinois, our Ranking Member,
 Mr. Lipinski.

TESTIMONY OF

CALVIN JENKINS

ACTING ASSOCIATE DEPUTY ADMINISTRATOR OFFICE OF GOVERNMENT CONTRACTING AND BUSINESS DEVELOPMENT U. S. SMALL BUSINESS ADMINISTRATION

THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

BEFORE THE

HOUSE SMALL BUSINESS COMMITTEE'S

SUBCOMITTEE ON WORKFORCE, EMPOWERMENT, AND GOVERNMENT PROGRAMS

NOVEMBER 8, 2005

Madam Chairman, Ranking Member and distinguished members of the subcommittee, thank you for inviting SBA here today to discuss the Small Business Innovation Research (SBIR) Program. I am Calvin Jenkins, Acting Associate Deputy Administrator for the Office of Government Contracting and Business Development at the U.S. Small Business Administration (SBA). I oversee the Office of Technology, which administers the SBIR program.

The SBIR program, established in 1982 by P.L. 97-219, was designed to "strengthen the role of innovative small business concerns in federally-funded research/research and development (R/R&D), and to utilize federal R&D as a base for technological innovation to meet agency needs and to contribute to the growth and strength of the Nation's economy." This competitive grant program is operated by 11 agencies, and has awarded more than \$16.9 billion to SBIR firms since its inception.

Program Structure

Each Federal agency with an extramural research or R&D budget in excess of \$100 million, is required to set aside 2.5% of that budget for the SBIR Program. The 11 participating agencies are: the Departments of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, Transportation, and the Environmental Protection Agency, the National Aeronautics and Space Administration, and the National Science Foundation.

The Program is structured in three phases: Phase I awards provide up to \$100,000 to evaluate the feasibility and the scientific and technical merit of an idea. Phase II awards are funded up to \$750,000 for 2 years for the further development of the ideas proposed in Phase I. Phase III is the commercialization phase, and no SBIR funds are utilized. In Phase III, the awardee firm must either secure private sector investment to bring the innovation to market or obtain follow-on contracts with Federal Agencies to meet specific Agency technology needs.

SBA's Role

SBA's role in the SBIR program can be summed up into four main categories: policy direction and program development; oversight of agencies for compliance with the policy direction; reporting program information as required by statute; and outreach and marketing of the program.

In setting policy for the Program, SBA issues a Policy Directive for the program which provides the rules and guidelines that Agencies follow as they manage their SBIR programs. The Directive contains detailed descriptions of procedures to be followed and guidance on all aspects of the Program. We revise the Policy Directive as needed to clarify Program issues or incorporate new elements into the Program.

The most recent revision to the Policy Directive was part of the implementation of Executive Order 13329 Encouraging Innovation in Manufacturing, signed by President Bush in February 2004. The Executive Order was predicated on the understanding that continued technological innovation is critical to a strong manufacturing sector and that the commercialization of technologies, products, or services funded through the SBIR Program plays a crucial role in stimulating the U.S. economy. The Order acknowledges that the R&D work performed by SBIR firms has contributed to our National defense, improved our health and welfare, protected the environment, and improved our production processes. To implement the Executive Order, SBA worked with the participating agencies to develop action plans that give high priority to manufacturing-related R&D. Agencies are now supporting this Executive Order by issuing solicitations specifically on manufacturing-related topics, giving priority to manufacturing-related projects as appropriate in the proposal selection process, and conducting extended outreach to foster manufacturing-related R&D.

In conducting compliance oversight activities, SBA monitors the calculation of agency extramural budgets, ensures that agencies keep to their solicitation schedules and make timely awards, ensures that policies, rules, or interpretations promulgated by an agency

are consistent with the SBIR Policy Directive, and conducts quarterly meetings with SBIR Program Managers. The quarterly meetings provide the opportunity to keep Program Managers abreast of interpretations of the Policy Directive, discuss pending SBIR legislation and issues impacting individual agencies, and hear directly from the Program Managers any concerns or difficulties they may be having.

In reporting program information, SBA maintains the Tech-Net database and reports annually to Congress on each agency's SBIR Program achievements.

In addition to providing program oversight, SBA develops and administers information and outreach programs for the Program and maintains a source and information file of interested small businesses. SBA is a regular contributor to numerous conferences and workshops held around the country.

Finally, the SBA is currently coordinating with the Office of Management and Budget on an assessment of the effectiveness, management, and performance measurement of the SBIR/STTR programs at the Department of Defense, National Aeronautics and Space Administration, Department of Energy, National Institutes of Health, and National Science Foundation. We expect to use the findings of that assessment to address any shortcomings in these programs.

Agencies' Role

Each of the 11 participating Agencies is responsible for the administration and management of its SBIR program. Agencies post SBIR solicitations, receive and evaluate proposals, select awardees, monitor projects, conduct reviews, require a commercialization plan with each proposal submitted for Phase II award, collect and maintain awardee information, administer their own SBIR funding agreements, ensure rights in data developed under the SBIR awards are properly protected, and they submit annual reports to the SBA containing complete records of their awards. Each agency has its own technology needs, consistent with its mission, as well as its own set of regulations and protocol. As a result, the SBIR program as a whole encompasses 11 very different types of SBIR programs. One important distinction is between agencies with clear technology needs such as DoD and NASA, and agencies that do not procure technology themselves but rather have broader public interest missions, such as NSF or NIH. These programs are run in very different ways, yet they all conform to the rules and framework we establish in the Policy Directive.

The number of awards has grown over time in proportion to the extramural R&D budgets of the participating agencies. More than 82,000 awards have been made over the life of the program, totaling \$16.9 billion. Minority/ disadvantaged firms have received 10,074 awards, representing 12.1 percent of all SBIR awards. Awards have been made to firms in all 50 states, Puerto Rico and the District of Columbia. Today, agencies evaluate over 30,000 proposals and make over 6,000 awards to about 3,000 small high-tech companies each year.

Quantitative measures of the program's success and impacts are essential. New data collection systems are being put in place, and new measures are being developed. Past assessments of the commercialization rate of the SBIR program conducted by the GAO, DoD, and SBA have found that about 40 percent of Phase II SBIR projects have resulted in commercial products. These assessments consisted of extensive surveys of past SBIR Phase II recipients where respondents were asked is they had had commercial sales that they attributed to the work they did under the SBIR award. When the question included not only sales but also additional investment received to continue the work, the percentage rose to about 55 percent. These commercialization rates are in the ballpark of what we would expect from a program funding early-stage innovation. Currently, we estimate that the average commercialization rate across all agencies is close to 40 percent.

We are currently implementing an online reporting system, through an enhancement of our existing TechNet system, to collect this information on an annual basis across all agencies. This should increase the reliability of the data, and enable us to develop new measures of commercial success and critical program outcomes in the future. We look forward to the suggestions and insights from the National Research Council review. As part of SBA's efforts to identify and improve the measurement of SBIR program impacts, we are currently planning an initiative to investigate and clarify the role that small firms actually play in the process of technological innovation. With a clearer view of this role, we will be better positioned to develop improvements to the SBIR program and to pursue other policies to stimulation innovation through small businesses.

Quantitative measures will never be able to capture or reflect the full range of impacts of innovation programs like the SBIR. Case studies, however, can often tell much of the story. We would like to mention just two such stories:

Sea Sweep, Inc, a Colorado based firm received an SBIR award from the Environmental Protection Agency (EPA). It utilized the award to develop and commercialize an innovative absorbent called Sea Sweep that functions both on land and water to absorb spilled oil and chemicals. The absorbent is made using a patented process that involves heating sawdust to a temperature at which the oil-like pyrolysis products render it very attractive to oil, but so repellent to water that it floats for many days. It absorbs the oil or chemicals immediately upon contact, and will float indefinitely in water, preventing environmental damage to marine life and bird species.

SBIR funding enabled Sea Sweep to evaluate the performance of this absorbent using various types of sawdust to determine which is most effective for absorbing oils and chemicals. Sea Sweep found that softwood sawdust is optimal in performance, availability, and cost. The tests also demonstrated that Sea Sweep absorbs almost all chemicals, including antifreeze and some strong acids. Saturated Sea Sweep can be burned as fuel for power plants or industrial furnaces.

In terms of commercial success, Sea Sweep is marketed in the US, Europe, South America, Australia, New Zealand, Japan, Indonesia, and the Persian Gulf. It has been

recognized by R&D Magazine as one of the 100 most technologically significant new products of the year.

Another SBIR success story is Containerless Research, Inc., an Illinois based firm that received SBIR funding from the National Aeronautics and Space Administration (NASA) to evaluate the liquids formed during the processing of semiconductor materials.

Work has resulted in refinement of techniques to study deeply undercooled liquids coupled to x-ray sources. As a result of work performed early in the project, the apparatus and technology to perform these difficult measurements have been refined, leading to expanded research and investigations into a wide array of difficult and complex liquid systems with the aid of x-ray diffraction. Research applied an apparatus for maintaining liquids under containerless conditions at extremely high temperatures. Various technical papers have been published on subject research.

The company has been able to commercialize its research by selling custom versions of the developed apparatus.

Commercial success of SBIR projects is often determined not by actions taken in Washington, but by the resources and infrastructure available to the small business in its home state. Because of this, SBA works with organizations at the state level to encourage the development of innovation infrastructures to help SBIR firms after Phase II. Many states have programs to provide small firms such as SBIR awardees with a range of business assistance services including business mentoring, matching the firms with venture capital companies or angel investors, providing basic business training, and integrating the projects with resources and expertise at Universities and other research institutions. While we communicate regularly with many state-level organizations on these issues, we recognize the need to better coordinate state-level commercialization infrastructure efforts on a national level. This would improve the chances of commercialization of SBIR technology, thereby leveraging the public's initial SBIR investment. At SBA, we are currently developing a strategy for this initiative.

Thank you for the opportunity to appear before you today. We will be happy to answer any questions you may have.

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TESTIMONY OF

FRANK M. RAMOS

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(ACQUISITION, TECHNOLOGY & LOGISTICS)

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Overview of the Department of Defense Small Business Innovation Research (SBIR) Program

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Chairman Musgrave, Congressman Lipinski and Members of the Committee:

Thank you for the opportunity to appear before you and discuss the health and well-being of the Small Business Innovation Research (SBIR) Program. I welcome this opportunity because I know you are committed, as am I, to providing our soldiers, sailors, marines and airmen with the best technology and products this nation is able to provide. Likewise, it is our obligation as leaders, decision makers, and policy developers to ensure that we are using taxpayer dollars as productively and efficiently as possible for their intended purpose. In that vein, today I will summarize the structure of and participation within the Department's SBIR Program; describe the methodology of topic generation and review leading to the selection of contract award recipients; and characterize output of the program to include aggregate commercialization results and success stories. I will also highlight actions the Department has undertaken to improve the effectiveness of our Program.

Before I address those areas, I am delighted to join my colleagues from the

Department of Energy, the Department of Agriculture, and the National Science

Foundation here today. We are all working within our respective agencies and with the

Small Business Administration (SBA) to ensure that the SBIR Program is as effective as

it can possibly be.

I would like to take just a few minutes to recognize the efforts of our DoD SBIR program managers and the civilian and uniformed technical representatives and contracting officers, as well as contractors that support them. These dedicated, professional individuals work hard, day in and day out, to ensure that our SBIR dollars are spent on the most promising and relevant technologies. They don't always see immediate results from their labors—that is the nature of early-stage research and development (R&D). However, the fruits of their labor can be seen saving lives and contributing to a wide variety of missions in Iraq, Afghanistan and around the world, including humanitarian relief efforts associated with the tsunami in Southeast Asia, and enabling relief efforts in the wake of hurricanes in the southeastern United States. We need not look further than these places to see that the program is making a positive impact, and that is due directly to their efforts. The Department also sees the opportunity for improvement as we look to the future. We are on a clear path to achieving evergreater, world-class warfighting capabilities though the SBIR Program and to extending our comparative technological advantage.

Current DoD SBIR Program Implementation and Participation

The SBIR Program is a major, strong element in achieving two of the

Department's goals: assuring technology dominance and enhancing the industrial base.

The broad mission of our SBIR Program is to advance technology development for the warfighter and the nation. Specifically, consistent with statute, this means to seed technologies through small firms which will eventually provide a material solution to our

nation's warfighting soldiers, sailors, marines and airmen, either directly as a product or service, or as part of a larger system.

The DoD SBIR Program encompasses ten constituent Military Service and Agency programs. The participating Services and Agencies, hereafter in this testimony referred to as "Components," include, in order of largest to smallest budget in fiscal year (FY) 2005 the: Air Force, Navy, Army, Missile Defense Agency (MDA), Defense Advanced Research Projects Agency (DARPA), Office of the Secretary of Defense (OSD), Joint Office of Chemical and Biological Defense, US Special Operations Command, Defense Threat Reduction Agency, and the National Geospatial-Intelligence Agency. The Department's SBIR budget is determined by a statutory 2.5 percent assessment of its extramural research, development, test and evaluation (RDT&E) appropriations; each Component's portion of the program is managed to be responsive to its specific mission and corresponding technology development needs.

In terms of budget, the Department's Program represents over 50 percent of the total federal SBIR budget, which now exceeds two billion dollars. The DoD SBIR Program has experienced astounding growth over recent years, doubling in size from FY 1999 to FY 2005 to over one billion dollars. This expansion is driven directly by growth in underlying RDT&E appropriations, as the set-aside percentage has remained constant over this period of time. This has driven overall program growth—the number of topics against which proposals are sought, the number of proposals received, and the total

¹ Extramural is defined as the sum of the total RDT&E obligations minus amounts obligated for such activities by employees of the participating agency in or through Government-owned, Government-operated facilities.

number of awards have all increased dramatically. In FY04, 1,082 topics generated 15,681 proposals, and 2,075 Phase I and 1,173 Phase II contracts were awarded to a total of 1,594 different firms.

Which firms received these contract awards? The recipients are all types of technology-focused firms from across the country. To a great extent, these are very small firms! In FY 2004, over 50 percent of Phase I contracts were awarded to firm with fewer than 25 employees, and over 30 percent were awarded to firms with fewer than 10 employees. This shows that, to a great extent, the Department is tapping entrepreneurial and start-up firms, which tend to offer the most ground-breaking, "out-of-the-garage" innovation. Also importantly, the DoD SBIR Program is an effective entry point for firms new to the defense business—those seeking to develop a military customer base. In FY 2004, 39 percent of SBIR Phase I award winners were first-time DoD contractors. And among the rest of the firms receiving Phase I awards in FY04, 79 percent had previously been awarded five or fewer Phase II contracts. Based again on FY04 data, 19 percent of Phase I award winners were minority- or women-owned firms, indicating that a significant portion of resources is utilizing this segment of the business base, consistent with one of the four primary statutory goals of the SBIR Program.

When we look at the DoD SBIR Program, we can see we are dealing with a very large enterprise. To appropriately manage these activities, we have two fundamental responsibilities:

 To make the best possible small business technology investments for our warfighters with the resources the Congress provides us, and; To be faithful stewards of those resources and ensure the taxpayers are getting the most value for their money.

I have briefly highlighted the scope of the DoD SBIR Program associated with the first responsibility. Let me take a few minutes now on the second area and describe how we are being a good steward of taxpayer dollars. I will then talk about some of the program results that demonstrate this stewardship.

The DoD SBIR Process and Selection Methodology

The Department interacts with industry via contracts while many other agencies utilize grants, or a combination of grants and contracts. As such, the DoD SBIR Program solicitations and subsequent source selections leading to contract awards are conducted in full compliance with the Federal Acquisition Regulation, the Defense Federal Acquisition Regulation Supplement and other DoD and Component contracting and source selection guidance.

The process begins with the generation and review of topics addressing a specific DoD R&D requirement. Each of the ten DoD Components generates topics relevant to their respective mission needs. These topics are submitted to OSD for review to ensure overall quality, consistency with the SBIR program's statutory mandate and overarching DoD technology objectives, and identify and resolve duplication of effort. Additionally, topics are reviewed for clarity to be easily understood by small firms with limited experience in the defense market.

For efficiency and to simplify market interaction with the Department, all approved topics are brought together into one solicitation and pre-released to the public

for a six-week period. During this period, interested firms may seek additional technical information as necessary to clarify the topics from the technical points of contact (normally the topic author). The solicitation then opens for a four-week period during which proposals are received.

After the solicitation closes, all proposals are reviewed by government scientific and technical personnel. Evaluation criteria include, in order of decreasing weight:

- soundness, technical merit, and innovation of the proposed approach and its incremental progress toward topic or subtopic solution;
- qualifications of the firm and team to perform the research and development and commercialize the results, and;
- the commercialization² potential of the proposed solution.

Firms with four or more prior SBIR Phase II contracts are assigned a Commercialization Achievement Index (CAI) score, which is a measure of how well the firm has commercialized prior SBIR technology relative to peers with the same number of Phase II awards. Firms with a CAI in the lowest tenth percentile—those with the worst record of commercialization—receive fewer points in source selection.

For SBIR Phase I, this whole process happens three times per year and once for

² Commercialization refers to the process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others), to government and/or non-government markets. Funds data reported as commercialization includes the receipt of money for the performance of follow-on R&D (as government-supplied Phase III funds or other sources) and the collection of funds from investors. A related term is SBIR Phase III, which refers specifically to work that derives from, extends, or logically concludes effort(s) performed under prior SBIR funding agreements, but is funded by sources other than the SBIR program. Phase III work is thus typically oriented toward commercialization of SBIR research or technology. The terms are often used synonymously and interchangeably when describing outcomes beyond SBIR Phase III.

the Small Business Technology Transfer³ Program. SBIR Phase II proposals are received on a continuous basis in response to Component invitations. Topic generation and review, as well as solicitation pre-release, release and proposal submission are entirely electronic, conducted through the DoD SBIR Worldwide Web site (www.dodsbir.net).

The DoD SBIR Program is highly competitive. Approximately one out of ten
Phase I proposals is selected while about one of every two Phase II proposals is selected
for funding. These selection rates indicate that only the best proposals are funded in
Phase I, and only the "best-of-the-best" go on to Phase II. Between FY02 and FY04, the
number of Phase I contracts awarded has remained relatively flat, albeit a very large
number, while the number of Phase II contracts has increased substantially. This shows
that the Department is focusing additional resources to advance a greater number of
identified technologies, bringing them closer to an operational impact in the form of
products or services for the warfighter and other non-Defense customers.

Gauging Program Success

In recent and past reports, the Government Accountability Office (GAO) has recognized that the SBIR Program seems to be meeting its statutory goals, but effectively measuring commercialization remains a challenge.⁴ The high watermark for SBIR success in the Department is bringing leading-edge technology solutions to the warfighter

³ The Small Business Technology Transfer (STTR) Program was established by the Small Business Research and Development Enhancement Act of 1992 (P. L. 102-564) and reauthorized in 2001 by P. L. 107-50. In most ways, it is identical to the SBIR program. Key distinctions are that the STTR program requires at least 30 percent of the work be performed by a not-for-profit research institution for the purposes of moving ideas from these research institutions to market, enabling researchers to pursue commercial application of technologies, and bridging the funding gap between basic research and a commercial product.

by leveraging the unique, entrepreneurial power of small businesses. Although there is no way to measure the monetary value of a technology that saves a life in combat or contributes to victory on the battlefield, we can and do measure program output in the form of both documented success stories and commercialization data.

The Department collects commercialization data from firms on all Phase II contracts and asks firms to keep this data current. Updates are requested when firms submit proposals. Additionally, we recently completed a comprehensive update of the entire database. Both the strength and weakness of this data set is that it is self-reported by firms. The Department is thus reliant upon them to report accurate and timely figures. A drawback is that we do not capture commercialization accruing to firms which have "graduated" from the program, growing to be ineligible for future awards either through organic expansion or via acquisition. Such commercialization may be quite substantial, rendering our data a conservative estimate of program impact. Despite this limitation, total reported product sales resulting from Phase II investments of \$6.6 billion in fiscal years 1991-2003 amounted to \$5.4 billion, and additional R&D and capital investment amounted to \$4.1 billion.

Some additional notes on the character of this commercialization will provide a greater appreciation for the program. A surprising 47 percent of total reported commercialization is attributable to private sector non-Defense applications representing a high degree of "spin-off." Historically it takes between eight and nine years from the

⁴ See GAO-05-861T - Observations on the Small Business Innovation Research Program, Statement for the Record of Anu K. Mittal, Director, Natural Resources and Environment Team, June 28, 2005; Testimony before the Subcommittee on Environment, Technology, and Standards, Committee on Science, House of Representatives.

point of Phase II award for additional sales to eclipse additional investment, showing that patience and persistence on the part of the performing firm are required to realize the full potential of their work. Finally, total commercialization exceeds total budget for each fiscal year's Phase II projects with about a four-year lag to generate the commercialization.

In addition to measuring financial success, we track program success stories, which demonstrate in a more concrete way the impact the SBIR Program has on specific customers. Perhaps the most vivid example of such a success story is Small Arms Protective Inserts (SAPI) and Enhance Small Arms Protective Inserts (E-SAPI) plates, which protect warfighters in theaters of operation from assault rifle and other small arms fire. Based on work done under FY 2000 and FY 2003 Navy SBIR contracts for vehicle armor, and a significant amount of follow-on research and development, ArmorWorks, Inc. of Tempe, Arizona developed high technology body armor plates for the Interceptor Body Armor System using advanced ceramic materials. To date, the firm has supplied over 300,000 ceramic armor plates for use in personal (SAPI and E-SAPI), vehicular and aircraft applications, saving lives of U. S. warfighters everyday.

A second excellent example of a success story is the Army SBIR originated Cockpit Air Bag System, designed and manufactured by Simula, Inc of Phoenix, Arizona. Composed of air bags, gas generators, and a unique three-axis crash sensor, the system is designed to protect helicopter aircrew from potentially fatal impacts in the event of a crash. The Army, Navy, Air Force, and Federal Aviation Administration all participated in the Joint Development of this system leading to a 2001 production contract. Simula,

Inc. has already fielded the system on over 400 DoD aircraft with hundreds of additional systems on order.

A third example of a success story is the Phraselator, a hand-held speech translation device developed by Marine Acoustics, Inc. (MAI), a veteran-owned small business based in Middletown, Rhode Island, through a FY 2001 DARPA SBIR effort. Following the terrorist attack in September of 2001, just seven months into their Phase II contract, DARPA requested that MAI accelerate development of a prototype Phraselator. MAI proved quite capable, delivering 200 prototypes in a matter of weeks to US military forces for use in Afghanistan during Operation Enduring Freedom. Phraselators are in use in Afghanistan and Iraq, where over 350 units are deployed and were used extensively in tsunami relief efforts. There is a large potential commercial market for the devices which are particularly helpful in law enforcement and medical applications where situational urgency may not allow time for an interpreter to arrive on the scene.

A final success story I'd like to highlight involves a Newport Beach, California firm, SRS Technologies. The Systems Technology Group of SRS based in Huntsville, Alabama, working under a SBIR Phase II contract with the Materials and Manufacturing Directorate of the Air Force Research Laboratory and the Office of the Secretary of Defense, developed a portable, very high bandwidth satellite communications antenna. In the destructive wake of Hurricane Katrina, SRS brought the antenna system to Biloxi, Mississippi to provide communications for local first responders. The antenna systems enabled them to establish a law enforcement command post and refugee information center. So impressive were the antenna's capabilities that the Federal Emergency

Management Agency and the Red Cross inquired about purchasing some to support their operations.

Improving the SBIR Program

We have taken numerous steps to improve the effectiveness and impact of our SBIR Program.

- In the summer of 2005, we began sponsoring an annual SBIR "Phase II &
 Beyond" conference to bring together SBIR Phase II firms with potential prime
 contractor partners, acquisition community buyers and financial community
 investors to facilitate matchmaking and relationship building to enable technology
 transition.
- We are increasingly selecting firms most capable of commercializing the results of their work by using a commercialization score in source selection.
- We are co-funding with several other agencies a multi-year National Research Council study of the program called for in the FY 2000 SBIR reauthorization. Their report is in draft form and we expect to see results from this comprehensive review by late next year. We've also commissioned a series of studies with the RAND Corporation to assess the DoD SBIR Program and make recommendations on how to improve it, focusing particularly on how to improve connectivity to major defense acquisition programs.
- We introduced acquisition program office endorsement and sponsorship of topics to more closely connect program output to the technology needs of programs of

- record. Over recent years, more than 50 percent of topics have had such sponsorship or endorsement.
- Phase II Enhancement Programs, established throughout our Program, offer SBIR
 matching funds to firms that attract additional funds from third party sources, such
 as acquisition program offices.
- We established a "Fast Track" program to offer Phase I SBIR contractors that
 obtain outside investment funding an expedited Phase II proposal evaluation and
 selection process, and funding to bridge the gap between Phase I and Phase II.

Additionally, several DoD Components have undertaken initiatives to improve the results of their respective programs. For example, the Navy funds a Technology

Assistance Program to enhance the commercialization efforts of interested Phase II firms and helps them market to acquisition programs. The Navy also has an initiative to increase prime contractor and systems integrator awareness of the SBIR Program to better use the SBIR technologies. The Army is actively coordinating generation and management of SBIR topics and projects within acquisition program offices. This increases the direct connection of program output to the needs of programs of record.

The Air Force has established an on-line "shopping mall" containing summary information characterizing key aspects of the SBIR technologies for potential customers and users (www.sbirsttrmall.com). MDA and DARPA enhance commercialization of their programs through partnerships with the National Technology Transfer Center and the Virginia Center for Innovative Technology, respectively.

The Small Business Administration is currently coordinating with the Office of

Management and Budget on an assessment of the effectiveness, management and performance measurement of the SBIR/STTR programs at the DoD, NIH, NSF, DoE, and NASA. We expect to use the findings of that assessment to address any shortcomings in our program, and to develop robust outcome measures.

Conclusion

In summary, again I thank you Madam Chairman for the opportunity to testify today on the SBIR Program. I hope my testimony has provided you with a clear understanding of how we run the SBIR Program. Additionally, I hope this has given you a sense for its importance to our nation's warfighter. I believe our actions relative to the SBIR Program are responsive to the demands of the taxpayers, and are consistent with the intent of Congress. I look forward to continuing to work with you and other members of Congress to improve our program and processes.

I would be happy to answer any questions you and the Members of the Committee may have.

Statement by

Dr. James Decker

Principal Deputy Director Office of Science, U.S. Department of Energy

Submitted to the

Subcommittee on Workforce, Empowerment and Government Programs Committee on Small Business United States House of Representatives

November 8, 2005

Madam Chairman and Members of the Subcommittee: Thank you for inviting me to speak today about the Small Business Innovation Research (SBIR) program at the Department of Energy (DOE).

The Office of Science manages the SBIR program for the Department and has done so since the SBIR program was formed in 1982. In addition to the Office of Science (SC), six other DOE programs participate in the SBIR program: Fossil Energy, Energy Efficiency and Renewable Energy, Nuclear Energy, Environmental Management, Defense Nuclear Nonproliferation, and Electricity Delivery and Energy Reliability. Some areas of the Department are exempt by law and do not contribute to SBIR, including the Naval Reactors and national security programs.

The statutory SBIR program has several purposes: (a) to stimulate technological innovation; (b) to use small businesses to meet Federal research and development (R&D) needs; (c) to foster and encourage participation by socially and economically disadvantaged small businesses; and (d) to increase private sector commercialization of innovations derived from Federal research and development.

The Department's SBIR goals include: 1) funding high quality projects with relevance to the Department's mission needs; 2) increasing private sector commercialization of technology developed through DOE SBIR-supported R&D; 3) stimulating technological innovation in the private sector; and 4) improving the return on investment from federally-funded research for economic and social benefits to the nation.

In accordance with the U.S. Small Business Administration's (SBA) SBIR Policy Directive, the SBIR program is administered in three phases. Phase I is to evaluate the scientific or technical merit and feasibility of ideas that appear to have commercial potential. Phase II builds on Phase I work and encompasses the core of the research and

development effort. Phase III refers to work that derives from, extends, or logically concludes efforts performed under SBIR funding agreements, but is not itself funded by the SBIR program. Phase III work is typically oriented towards commercialization of the SBIR research or technology. That is, the SBIR funding pays for research or R&D meeting DOE objectives identified by the DOE (Phases I and II); non-SBIR capital provides follow-on developmental funding to meet commercial objectives (Phase III).

The Office of Science also manages the Small Business Technology Transfer (STTR) program, which was established in 1992. The major difference between the SBIR and STTR programs is that STTR grants must involve substantial cooperative research collaboration between the small business and a research institution. At least 40% of the research or analytical effort must be allocated to the small business, and at least 30% of the effort must be allocated to a single research institution. The budget for DOE STTR program is also much smaller than SBIR. In FY05, the STTR program was funded at \$12 million, while the SBIR program was funded at \$101.4 million.

SBIR PARTICIPATION

Over the twenty-three years of its existence, the SBIR program has matured and evolved significantly. We have issued twenty-four Phase I solicitations, reviewed approximately 30,410 proposals, and selected for funding 4,123 Phase I projects and 1,677 Phase II projects. Each year we have issued the solicitation on schedule, met the deadline for the selection of both Phase I and Phase II awards, and published abstracts of our Phase I and Phase II projects.

The SBIR budget for Fiscal Year 2005 was \$101.4 million. The Department received 1,490 Phase I grant applications from 823 companies of which 1,037 were sent out for external peer review. We selected 259 applications for Phase I awards resulting in grants to 179 small businesses in 35 states. Eighty-five of the 259 grantees were first time winners with DOE. Twenty-six of the applicants selected for funding were from socially and economically disadvantaged small businesses and seven were from small businesses located in a HUBZone (historically underutilized business zone).

Below are additional statistics from prior years:

Year	Number of Application Submissions	External Peer Reviewed	Number of Awards	Number of Individual Companies that Submitted	Number of Companies with Funded Projects	First-time Awardees	Economically Disadvantaged Small Business Awardees	HUBZone Awardees
2004	1312	857	247	736	187	83	31	4
2003	1186	738	219	678	181	72	27	8

PROGRAM EFFECTIVENESS

Performance of the SBIR program compares favorably to other research programs that fund basic and applied research. The DOE SBIR program has supported excellent research, resulting in spin-off companies and technologies, and is a model with respect to the commercialization assistance program. According to the SBA, DOE was the first agency to offer commercialization assistance to awardees beginning in 1990.

Several comprehensive reviews of the SBIR program by the Government Accountability Office (GAO) have found it to be successful in enhancing the role of small businesses in Federal R&D, stimulating commercialization of research results, and supporting the participation of small businesses (Testimony Before the Subcommittee on Environment, Technology, and Standards, Committee on Science, House of Representatives, *Federal Research: Observations on the Small Business Innovation Research Program*, June, 28 2005, GAO-05-861T, and references therein). Awards from the SBIR program help small businesses attract investment by affirming that the companies have excellent technical capability, thus reducing some of the uncertainty involved in early-stage investment.

PROGRAM MANAGEMENT OVERVIEW

Following the establishment of the SBIR program in 1982, an Action Memorandum to the Secretary of Energy from the Director of the Office of Small and Disadvantaged Business Utilization (OSDBU) considered several options for the organizational placement of the SBIR office. The decision was to place the program in the Office of Energy Research (OER), now the Office of Science, "since OER: 1) is the focal point in the Department for R&D strategies, plans, policy, and technology programs in all energy disciplines covered by Public Law 97-219; 2) controls almost one-half of the entire departmental R&D budget; and 3) represents the Department in Federal R&D coordination activities, including the President's Council for Science, Engineering and Technology."

The Memorandum noted, "Public Law 97-219 mandates a federally supported, high technology program for small business concerns, under which implementation and placement can best be accomplished by a technology-based outlay office with crosscutting R&D responsibilities."

The SBIR program complements the Department's other R&D funding mechanisms. SBIR is regarded within the Department like any other R&D program, namely, as a vehicle by which the Department accomplishes its R&D objectives. About 70 percent of the funds from the set-aside for the SBIR program come from the Office of Science (SC), which has vast experience in managing research programs. SC's long history of using merit-based review of grant applications and its thorough understanding of scientific and technical research are key elements in our successful management of the SBIR program. The SBA SBIR Policy Directive encourages agencies to use their routine review processes for SBIR grant applications. In particular, the Policy Directive points out that peer reviews external to the agency are authorized. Therefore, as with other SC programs

the scientific/technical evaluations of SBIR grant applications are performed by external researchers expert in the subject area. SC's relationship with the scientific community, from which the peer reviewers are drawn, is extensive.

Cooperation throughout the Department in administering the SBIR program is achieved through a balance of centralized and decentralized management. The SBIR program is centralized in the setting of schedules, procedures, scoring guidance, final award selections, and all logistics relating to the processing of proposals. It is decentralized in that the technical program offices are responsible for developing specific research topics that support their mission goals, identifying peer reviewers, and providing a priority ranking of grant applications to be considered for funding.

Examples of current technical topic descriptions are as follows:

- Research to Support Proliferation Detection
- · Electric Transmission and Distribution Technologies
- Decontamination and Decommissioning of Facilities in the DOE Complex
- Biological Solutions for Reducing Atmospheric Carbon Dioxide and for Producing Fuels
- Coal Gasification and Combustion Technologies
- Nanotechnology
- · Neutron, Electron, and Photon Beam Instrumentation
- Advanced Technologies for Nuclear Energy
- · Renewable Energy Sources
- Fusion Science and Technology
- · Advanced Concepts and Technology for High Energy Accelerators
- High-Performance Computing
- Nuclear Particle Physics and Radiation Detection Systems, Instrumentation and Techniques

Within the SBIR office, an oversight review of the scoring of SBIR grant applications is conducted to assure that any proposal recommended for funding is supported by the set of peer reviews for that grant application. We believe that SC's management practices, with its emphasis on quality science and technology, are critical to maintaining the integrity of this process.

METHODOLOGY FOR DETERMINING GRANT RECIPIENTS

The Department issues an annual combined solicitation for the SBIR and STTR programs. It typically contains approximately 50 research topics, and small businesses with strong research capabilities in science or engineering are encouraged to apply. The solicitation is advertised on Grants.gov, the Federal Government's Web Portal for all federal grant applications and also the Department's E-Center (http://e-center.doe.gov) for all Business and Financial Assistance opportunities available from the Energy Department. Applications are accepted electronically only.

Additionally, we use the internet, regional and national conferences, and trade journals to ensure the applicant community is well informed about SBIR and to encourage a high number of grant applications. The SBIR electronic mailing list consists of over 14,500 small businesses.

Phase I grant applications are judged on a competitive basis against other applicants within the same technical program area (e.g. Fossil Energy, Energy Efficiency, etc.) in several stages. First, all are screened initially by DOE technical managers to ensure that they (1) meet stated funding opportunity notice requirements; (2) are responsive to the topic and subtopic category; (3) contain sufficient information for a meaningful technical review; (4) are for research or for research and development; and (5) do not duplicate other previous or current work. Grant applications which fail to pass the initial screening are declined.

Second, grant applications that meet the conditions above are further evaluated by outside independent scientific and engineering experts who are selected by DOE technical program managers. The external reviewers evaluate each proposal in terms of the following criteria:

- 1. Strength of the Scientific/Technical Approach as evidenced by (1) the innovativeness of the idea and the approach; (2) the significance of the scientific or technical challenge; and (3) the thoroughness of the presentation.
- 2. Ability to Carry out the Project in a Cost Effective Manneras evidenced by (1) the qualifications of the Principal Investigator, other key staff, and consultants, if any, and the level of adequacy of equipment and facilities; (2) the soundness and level of adequacy of the work plan to show progress toward proving the feasibility of the concept; and (3) the degree to which the proposed project budget is justified by the research plan.
- 3. Impact as evidenced by (1) the significance of the technical and/or economic benefits of the proposed work, if successful; (2) the likelihood that the proposed work could lead to a marketable product or process; and (3) the likelihood that the project could attract further development funding after the SBIR project ends.

DOE makes selections for Phase I awards from those grant applications judged to have the highest overall merit within their technical program area, with approximately equal weight given to each of the criteria above. The DOE will not fund any grant application for which there is a reservation with respect to any of the three evaluation criteria, as determined by the review process. In addition, because the DOE has developed a process intended to support only high quality research and development, grant applications will be considered candidates for funding only if they receive strong endorsements with respect to at least two of the three criteria.

Third, from those grant applications considered candidates for funding following peer review, each of the participating DOE program areas make selections. Final decisions are made by the DOE SBIR/STTR Program Manager based on the recommendation of

the technical managers and consideration of other factors such as budget and program balance. On average, about 1 out of every 6 grant applications is selected for funding.

The Phase II methodology is the same, except that a commercialization plan is also evaluated as part of the Impact criterion. As with Phase I, Phase II grant applications are sent out for external peer review by independent experts. Phase II applicants must be DOE Phase I recipients. About 1 out of every 2 Phase II grant applications is selected for funding.

The Department's SBIR program does not provide funding for Phase III since it is statutorily prohibited; however, the program offers commercialization assistance to Phase I and II awardees, which is described later in the testimony.

DOE SBIR ADVISORY BOARD

Because the SBIR program impacts six DOE organizations in addition to the Office of Science, a Department-wide SBIR Advisory Board comprised of Deputy Assistant Secretary level representatives from each technical program that participates in SBIR was established in 1996. The purpose of the SBIR Advisory Board is to provide policy advice to the Director of the Office of Science on the conduct of the SBIR program.

All major policy decisions affecting the SBIR program receive the endorsement of the SBIR Advisory Board before being implemented. Over the years, the SBIR Advisory Board has expressed a high level of satisfaction with the management of the SBIR program within the Office of Science in cooperation with the program offices.

ALLOCATION OF FUNDING

The Department sets aside 2.5 percent of its extramural R&D budget (excluding naval reactors and weapons programs) to fund SBIR projects. Typically, about 25 percent of the funds are spent on Phase I grants, while 75 percent are used for Phase II, which is the major R&D effort. Each technical program area participating in SBIR is allotted its contribution of the set-aside to spend on projects pertaining to its particular research program, provided a sufficient number of high quality grant applications are available. The SBIR office oversight procedures assure that only high quality grant applications are awarded in each program area. The technical managers across the Department as well as the Advisory Board are very supportive of this funding allocation process.

COMMERCIALIZATION ASSISTANCE

A large majority of SBIR awardees have excellent skills in science and engineering research but lack experience in product development, financing business growth, raising venture capital, and marketing. In accordance with one of the statutory program purposes of increasing private sector commercialization of innovations derived from Federal R&D, the Department provides funding for commercialization assistance. The SBIR law allows each agency to use a portion of the SBIR set-aside funds for discretionary technical

assistance like commercialization. So companies participate in DOE's commercialization assistance services at no cost and the Department's participating research programs benefit from early introduction of mission-related technology into the marketplace.

One of the services provided to Phase II awardees is the Commercialization Opportunity Forum Program, which has been provided for 15 years. This program is conducted by Dawnbreaker, a private organization from Rochester, New York, competitively selected by and under contract with DOE.

As a result of participation in the 2002-2003 Commercialization Opportunity Forum, the most recent program for which analysis by Dawnbreaker has been completed, 48 percent of the small companies that participated have already received over \$47.5 million in either private sector investment (equity, licensing), non-SBIR Federal or state funding, or sales. We are unable to obtain from Dawnbreaker a further breakdown of this \$47.5 million Phase III result into Federal vs. non-Federal funding at this time.

The program takes eight months to complete and includes:

- Kickoff Meeting: Sixty to seventy SBIR/STTR awardees are invited to attend a kickoff meeting, led by Dawnbreaker.
- 2) Business Plan Development: For about four months, the SBIR participants work individually with one of Dawnbreaker's staff members to develop a business plan. A series of interim reports are produced, culminating in a draft business plan. Finally, the DOE, in consultation with Dawnbreaker, selects about 30 participants to present at the Opportunity Forum.
- 3) Advanced Commercialization Workshop: These remaining participants meet for an intensive two-day weekend workshop which includes one-on-one sessions with Dawnbreaker's staff. The output of the workshop includes improvements to the business plan and instructions for further refinements.
- 4) Business Plan Refinement and Preparation of Presentation Materials: For the next couple months, companies work individually with Dawnbreaker's staff to refine business plans and prepare presentations for the Forum.
- 5) Opportunity Forum: The Commercialization Opportunity Forum, which takes place over two days in a Washington area hotel, is designed to facilitate interaction between technology entrepreneurs, potential strategic allies, and investors through a combination of formal presentations and informal networking opportunities. In preparation for the Forum, the SBIR/STTR participating companies identify prospective investors and allies. Using these leads and others, Dawnbreaker is responsible for assuring that a sufficient number of upper level decision makers from appropriate partnering and funding sources attend the Forum. Two days before the Forum, companies attend a Presentation Workshop in which Dawnbreaker's staff work with them to polish their presentations and provide insight into the interests of the investors and strategic allies.

Other commercialization assistance is provided on a limited basis for those small businesses that are unable to devote a significant amount of time to participate in the Commercialization Opportunity Forum Program. These services are delivered through a competitively selected contract currently held by Foresight Science and Technology, Inc., located in Princeton, New Jersey and includes the following:

Trailblazer™ (Initiated early in Phase I to support Phase II application)

The TrailblazerTM develops market data and participation required for concurrent engineering-based product or service development. Both literature searches and interviews are conducted. The program runs six weeks and it helps businesses:

- 1) identify major market niches for commercialization;
- 2) determine key requirements and traits for market-viable products or services;
- 3) develop a value for the technology that gives it a competitive advantage; and
- 4) identify feasible vehicles for commercialization and map out a path into the market.

Virtual Deal Simulator™ (Initiated early in Phase II)

The Virtual Deal SimulatorTM (VDSTM) uses computer-based templates to explore commercialization deals by establishing a sequence of tasks for: 1) the completion of R&D; 2) transitioning the technology development into production; and 3) transitioning the technology product into the market. VDSTM also identifies critical path tasks and milestones for commercialization. The program helps to identify associated costs, required resources, outputs, and metrics for success, duration, and intellectual property concerns for each task, which can be used to track and evaluate post-deal progress. The VDSTM can also be used to identify potential technology, knowledge, and capability gaps in product development and in transitioning into the market and make suggestions for risk reduction. The duration of this program is six weeks.

Technology Niche AnalysisTM (Initiated mid-Phase II to identify Phase III partners)

The Technology Niche AnalysisTM (TNATM) assesses potential applications for a technology. Both literature searches and interviews are conducted. For each viable application, TNATM identifies:

- 1) the needs and concerns of end-users which drive the competitive opening:
- 2) competing technology and products;
- 3) the competitive advantage of the technology and market drivers;
- 4) key standards, regulations, and certifications influencing buyer acceptance;
- potential customers, licensees, investors, or other commercialization partners (targets as specified by participant preferences); and,
- a commercialization strategy, together with tasking and a schedule for implementation of the strategy and design suggestions for the product.

Targets are contacted to ensure they are viable leads and to collect important information for follow-up deal-making. Points of contact are included. This program lasts for six weeks

PROGRAM OUTCOMES

The quality of the research selected for awards has remained very high. I am very pleased that between 1986 and 2003 at least 25 of our projects (out of the 1384 Phase II projects funding during that period) have received R&D-100 Awards from Research and Development Magazine, which selects the 100 most significant technical products and innovations each year. Some examples include: "New Efficient Nanophase Materials for Blue and Deep Green Light-Emitting Diodes," Nomadics, Inc., Stillwater, OK (2004); "Optically Coupled High Power Inverter," Airak, Inc., Manassas, VA (2003); "The Development of A-SPECT," Photon Imaging, Inc., Northridge, CA (2001); "MOLYCAST Furnace," Micropyretics Heaters International, Cincinnati, OH (2001).

The DOE SBIR program conducts an annual survey of Phase II grantees, active and inactive. The survey requests companies to: (1) list all products and services derived from their DOE SBIR projects; (2) report on both sales and/or Phase III investment related to these products and services; and (3) identify which Phase II projects contributed to the development of the products and services. Approximately 90% of Phase II grantees respond to the annual surveys.

Survey data indicate that companies participating in the DOE SBIR program (23 years of awards, resulting in 1,191 projects) have received over \$1.6 billion in sales (\$0.24 billion from Federal and \$1.4 billion from non-Federal sources) and over \$1.3 billion in developmental funding (\$0.46 billion from Federal and \$0.88 billion from non-Federal sources) between 1986 and 2003. Companies have received approximately \$3 billion in Phase III funding (from sales or further development investment), which is more than double the cost of DOE SBIR/STTR funding over the life of the program (\$1.4 billion).

A relatively small percentage of these companies received a significant portion of the \$3 billion in Phase III funding. For example, if we use the total DOE SBIR funding of \$850,000 or more as the benchmark, 16% of the projects account for 73% of the Phase III funding. The survey data also indicate that only 61% of the businesses had received Phase III sales or further development investment. Similar to small start-up companies supported by non-Federal and venture capital funds, only a small percentage of the small businesses funded by the DOE SBIR program achieve large commercial successes.

Following are some examples of commercialization successes resulting from DOE SBIR grants.

Amonix, Inc. (Torrance, CA) received SBIR funding to develop a photovoltaic power system. Amonix's solar cells and photovoltaic (PV) systems have demonstrated unprecedented performance for both space and terrestrial solar power applications. As

early as the 1990s, Amonix had field-tested several integrated high-concentration photovoltaic (IHCPV) generating systems throughout the United States. Amonix has focused on utility-scale applications for solar generating systems. When deployed in bulk, the energy cost associated with IHCPV will be competitive with other generation options. The systems can be deployed as part of a centralized solar farm or can be used in distributed applications. Amonix currently has 650 kWs of power installed, including a farm installation at Arizona Public Service. Amonix has received equity financing of \$5 million and \$2.4 million in sales of their patented IHCPV systems.

AMAC International, Inc. (Newport News, VA) received SBIR funding to develop specialized high power radio frequency (RF) windows and corresponding input couplers. Both are hardware components that facilitate that transfer of radio frequency power from a source to the superconducting cavities of an accelerator. The reliability and cost effectiveness of high power RF windows and couplers are critical to the performance and future development of new accelerators in nuclear physics, high energy physics, and nuclear industries. Five input coupler prototypes have been fabricated and successfully tested and all designs meet DOE's Spallation Neutron Source (SNS) project requirements, with the support and collaboration of Communications & Power Industries, Inc. (CPI) and the DOE Jefferson Laboratory. SNS is an accelerator-based neutron source that will be used to study the structure and property of materials, including polymers and biological materials.

AMAC's success in the DOE SBIR project made it possible for the first time for an American company to win a high RF power window contract in an international competition. The AMAC hardware technologies have been licensed to CPI (the largest RF products manufacturer in the US), for their further marketing and development. The royalty from licensing is 8 percent. On a contract worth \$3 million dollars, AMAC will earn \$240,000.

Atlantia Offshore Limited (Houston, TX) received DOE SBIR funds to develop a tension leg platform concept for use in accessing deep water oil and gas reserves. The engineering firm developed the tension leg platform SeaStar as a result of the DOE SBIR funding. The SeaStar is designed to operate in water depths up to 10,000 feet with a payload up to 11,000 tons, thus allowing oil and gas development in new U. S. offshore fields in the Gulf of Mexico. Cumulative sales of Altantia's first four platforms are more than \$500 million. The company is now developing designs for even larger SeaStars, with payloads in excess of 25,000 tons. Currently, Atlantia is working with a major oil company to apply its SeaStar technology for offshore work in West Africa. The four SeaStar platforms already built by Atlantia provide the federal government with production and royalty payments estimated at \$100 million per year.

Deep Web Technologies (Los Alamos, NM) received SBIR funding to research and develop a web-based search tool with relevance-ranking of search results from multiple internet databases. This new technology sorts through selected databases and rapidly returns information in an order likely to meet the users' needs. Soon after its development, this technology was embraced by the U.S. government's interagency

Science.gov Alliance and applied to the interagency portal Science.gov, which makes available to the public reliable information resources selected by the respective agencies as their best science information. Science.gov was developed by an interagency working group of 14 scientific and technical information organizations from 10 major science agencies. Together these agencies make up the Science.gov Alliance. The Alliance and Science.gov were formed to improve and enhance access to information stemming from government R&D programs.

The version of the government's portal, which first introduced Deep Web Technologies' relevance ranking for multiple databases, was named Science.gov 2.0. Officially launched on May 11, 2004, Science.gov 2.0 introduced relevancy-ranking to the vast stores of government R&D results and searches the 47 million pages of government R&D results and presents the results to the users in relevancy-ranked order.

Diversified Technologies, Inc. (DTI) (Bedford, MA), founded in 1987 by graduates of the Massachusetts Institute of Technology, received SBIR funding to develop power modulators for linear colliders, a power supply for plasma heating, and high power switches for accelerators. DTI's core expertise lies within the application of solid-state devices, such as high power, high voltage opening and closing switches. DTI is the developer and marketer of the very successful PowerModTM line of products, which was selected twice by R&D Magazine as one of the most significant products of the year. The PowerModTM technology is widely recognized as a true breakthrough in high-voltage electronic design. DTI's PowerModTM technologies replace older components in sophisticated high voltage, high-power systems such as radar transmitters and particle accelerators and are emerging as essential components in power conversion. DTI has reported over \$10 million in sales for DOE SBIR-related projects.

NexTech Materials, Ltd. (Lewis Center, OH) received the DOE SBIR program to develop solid oxide fuel cell materials and manufacturing processes. NexTech is one of the only organizations in the world that is focused specifically on the development of this technology. NexTech Materials has been able to obtain over \$7 million in funding from various sources including state, federal, and private development, and has increased its workforce by more than one-third. NexTech has over 100 customers in more than 25 countries, and numerous development partners throughout the world. NexTech ultimately will position itself for strategic alliances with fuel cell power system manufacturers and/or raw materials suppliers in order to meet the volumes demands of expanding commercialization.

Examples of R&D Accomplishments Resulting from DOE SBIR Grants

Company	Technology/Process developed	Technology's purpose	Technology's application and benefit
Advanced Fuel Research	Optical technique for measuring radiative properties	Analysis of gases and surfaces	Better quality products for the semiconductor industry.
AMAC International, Inc.	Radio frequency windows	Longer-lasting, less expensive accelerator hardware components	Increase performance of accelerators for nuclear physics, high energy physics and industry
Amonix, Inc.	Photovoltaic Power System	Create cost-effective solar generating systems	Generation of clean, renewable power at low cost.
Atlantia Offshore, Limited	Floating platform	Enable deep water oil and gas drilling	Oil and gas development of new U.S. offshore fields in the Gulf of Mexico.
Ceramatec, Inc.	Shock resistant and temperature-tolerant ceramics	Components for diesel engines and diesel filters	Energy efficient engines and turbines.
Deep Web Technologies	Web-based search engine with relevance- ranking	Optimize desired search results in multiple database internet searching	Obtain desired information from publicly accessible government R&D databases
Duly Research	Photoelectron linear accelerator	Create a cost effective injector for use in accelerators	Improve future linear colliders, synchrotrons, X- ray sources for research and medical applications
Fuelcell Energy, Inc.	Ceramic fibers	Carbonate- based fuel cells	Increases life and availability of Direct FuelCell that can achieve electric efficiency greater than 70%.
MacConnell Research Corp.	Automated blood purifier for molecular biology applications	Smaller, faster, cheaper instrument for DNA purification and analysis	DNA sequencing, genomic research, drug development
Precision Combustion	Catalytic combustor	Reduce engine pollution of gas turbines	Cost-efficient retrofits of existing gas turbine engines to meet emission requirements.

POTENTIAL AREAS FOR IMPROVEMENT

While we have demonstrated that the current set-aside level is more than adequate to meet the needs of our program, we are interested in two small changes to how the available set-aside funds are allocated. (1) DOE SBIR Phase II recipients have indicated in qualitative surveys that the commercialization assistance programs and services offered by the DOE's SBIR program are valuable to their product development and commercialization efforts. Also, quantitative data from DOE's SBIR Opportunity Forum indicate that more than 50 percent of their graduates received follow-on investment within 18 months. If there is to be a growing emphasis on commercialization success in the SBIR program, then it seems reasonable to consider whether the provisions for discretionary technical assistance provided by the SBIR reauthorization legislation are sufficient. (2) Also worth examining is whether to allow a small fraction of the set-aside to be used for administration expenses for SBIR staffs to improve Phase III follow-up and provide better commercialization assistance to the small businesses. More robust data collection would enable us to better assess the results of the program, and to adjust our management practices as appropriate.

I believe the National Academies is evaluating these and other issues in their current study of the whole SBIR program, *Capitalization on Science, Technology, and Innovation: An Assessment of the Small Business Innovation Research Program*, and I look forward to the Academies' Report.

The Small Business Administration is currently coordinating with the Office of Management and Budget on an assessment of the effectiveness, management, and performance measures of the SBIR/STTR programs at DOD, NIH, NSF, NASA, and DOE. We expect to use the findings of the assessment to address any shortcomings in our program, and primarily to develop robust program performance measures.

CONCLUSION

The DOE SBIR and STTR programs currently provide over \$100 million each year to small businesses to help entrepreneurs take their ideas from conception to reality. The Department has, since the program's inception, made 4,123 Phase I awards and 1,677 Phase II awards with a total value of about \$1.4 billion. Of the Phase I awards, about 12 percent are made annually to socially and economically disadvantaged small businesses and about one-third are first time awardees with DOE. In return, these companies have earned more than \$3 billion in sales and additional development funding, created jobs, and helped the nation capitalize on its substantial investment in R&D. Approximately 53 percent of the Phase II projects have contributed to the \$3 billion in sales and follow-on investments.

The Department has also benefited from small business participation due to their contribution to the Department's mission in two ways: 1) the technologies the small businesses have developed and 2) the research and new knowledge gained from that research that contributes to the Department's R&D activities. Successful collaborations

between small businesses and the DOE R&D complex have provided new insights and innovative technologies that have advanced the Department's missions to improve the Nation's energy, economic, and national security. Small businesses are usually agile, tend to produce quickly with low overhead, and have demonstrated success in developing niche technologies, which often support the Department's larger projects. High-technology small business grantees, many of whom started in business as a result of SBIR awards, have become a valuable resource for solving high risk, high technology problems. Solving these high technology problems will continue to be essential to meeting the Nation's current and future energy challenges.



Testimony
Before the Subcommittee on Workforce,
Empowerment and Government Programs
Small Business Committee
United States House of Representatives

"The Small Business Innovation Research Program – Opening Doors to New Technology"

Statement of

Norka Ruiz Bravo, Ph.D.

Deputy Director for Extramural Research Office of Extramural Research National Institutes of Health U.S. Department of Health and Human Services



For Release on Delivery Expected at 10:00 a.m. Tuesday, November 8, 2005 Good Morning, Madam Chairwoman and Members of the Committee. I am Dr. Norka Ruiz Bravo, Deputy Director for Extramural Research at the National Institutes of Health (NIH), part of the U.S. Department of Health and Human Services (HHS).

The NIH is the nation's premier medical research agency. Our mission is the conduct of biomedical, behavioral, and clinical research to improve the health of the American people. Thank you for giving me the opportunity to provide you with an overview of the NIH Small Business Innovation Research (SBIR) Program. Today, I would like to focus on two areas of SBIR: first, the role it plays in the NIH research agenda; and second, several benefits of the program.

NIH and SBIR

The NIH is the principal operating component within HHS participating in the SBIR program. We constitute about 98% of the Department's entire SBIR program activity and contribute the second largest amount of SBIR funding available across the Federal government. In FY 2005, the NIH made 1,668 SBIR awards amounting to over \$626 million. About 21% of all Phase I SBIR applicants (Phase I determines scientific or technical feasibility and commercial merit.) and about 46% of all Phase II SBIR applicants (Phase II continues promising Phase I results.) were funded.

Across the NIH, there are 24 Institutes and Centers that reserve 2.5% of their extramural research and development (R&D) budget for SBIR awards. Each of these awarding components has a research mission with well-defined priorities. Examples of the breadth

and depth of research we support include biotechnology, pharmaceuticals, therapeutics, medical devices, nanotechnologies, bioengineering, and behavioral research.

The SBIR program has become fully integrated into the overall scientific programs and goals of the NIH, particularly with respect to the goal of translating scientific findings and advances into tangible products and services. Through a competitive, phased award system, the SBIR program supports a wide array of innovative biomedical and public health R&D projects by small firms. The SBIR program stimulates technological innovation in the small business research community and enhances collaborative efforts with the academic research community. The program encourages small businesses to explore their technological potential and provides the incentive to profit from its commercialization. The Nation benefits from the small businesses' entrepreneurial spirit, the end result of which is high technology innovation to meet specific R&D needs.

Program Benefits and Enhancements

The NIH SBIR program has evolved over two decades into a robust program of medical research awards. When President Reagan signed the SBIR legislation into law, he stated, "We in government must work in partnership with small businesses to ensure that technologies and processes are readily transferred to commercial applications." For more than twenty years, NIH has embraced the letter and the spirit of this law. We are pleased that our SBIR program has resulted in benefits to our agency as well as the medical research community and the American people. The NIH is currently coordinating with the Office of Management and Budget on an assessment of the

effectiveness, management, and performance measurement of the SBIR/STTR (Small Business Technology Transfer) Programs at the Small Business Administration (SBA), the Department of Defense, the National Science Foundation, the Department of Energy, and the National Aeronautics and Space Administration. We expect to use the findings of the assessment to address any shortcomings in our program, and primarily to develop robust outcome measures.

Today, the NIH serves as a keystone for translating scientific discoveries into tangible benefits. NIH research is paying enormous dividends: Americans are living longer, more productive lives; infant mortality rates have been reduced; and the quality of life has improved, as evidenced by the steady decline (1%-1.5% per year over the last two decades) in the number of elderly experiencing developmental, physical, and mental disabilities. The following are just a few examples of successful innovative SBIR projects that the NIH funded in the areas of vaccine development, surgical procedures, and medical devices that were deemed to have scientific merit and commercial potential under the NIH's rigorous, external peer-review process:

Vaccines. AVANT Immunotherapeutics (MA) has used the SBIR program to advance a revolutionary vaccine, designed to prevent or treat atherosclerosis (the hardening and narrowing of the arteries), into clinical trials. SBIR funds helped finance experiments demonstrating the feasibility of this vaccine concept. Following the success of those early experiments, significant additional work was done with this vaccine, both in research and development, and it has now entered into Phase I clinical trials. If clinical trials are

successful, this vaccine has the potential to greatly enhance the clinical management of atherosclerosis.

Surgical Procedures. IntraLase Corporation (CA) recognized the need for greater safety and precision in the first step of LASIK eye surgery. In answer to that, the company used the SBIR program to develop a femtosecond (one millionth of a nanosecond) laser to replace mechanical microkeratomes, the knives presently used in this surgery, to create a more precise and safer corneal flap. IntraLase virtually eliminates the severe sight threatening complications seen with the microkeratome, improving safety and precision while providing predictably better visual results for the patient. IntraLase is the most sophisticated and accurate technology for corneal flap creation available today and has given many patients greater confidence and assurance in choosing laser vision correction.

Medical Devices. Design Continuum (MA) used SBIR funding to create an innovative anesthetic gas delivery system, PediSedate, for children to help reduce the fear associated with medical procedures that require anesthesia. Providing medical treatment to children, particularly emergency procedures to treat trauma, can be exceptionally difficult. The anxiety children feel in such situations can make them uncooperative, and their typical fear of needles makes administration of painkillers challenging. Promising clinical results show that the PediSedate mitigates the traumatic experiences of children during anesthesia procedures.

To grow this long line of successes, the NIH has initiated several enhancements to our SBIR program over a number of years. These improvements are intended to help the small businesses opportunity for success while increasing the efficiency and effectiveness of our own SBIR program:

<u>Flexibility in cost and time.</u> NIH has recognized that not all types of biomedical and public health research can be accomplished through prescribed award levels and time periods, such as those specified in the SBA SBIR Policy Directive. And since once size does not fit all, we encourage small business concerns to propose a realistic budget and project period that is appropriate for the successful, not just timely, completion of the research project.

<u>Fast-Track</u>. To address the congressional encouragement to develop programs to reduce the gap in funding between SBIR Phase I and Phase II awards, the NIH Fast-Track mechanism is designed to expedite the decision and award of Phase II funding for scientifically meritorious applications for projects that have a high potential for commercialization. Fast-Track incorporates a submission and review process in which both Phase I and Phase II SBIR grant applications are submitted and reviewed together. The Phase I portion of a Fast-Track must specify clear, measurable milestones that should be achieved, as assessed by NIH program staff, prior to the issuance of the award initiating SBIR Phase II work.

Phase II SBIR Competing Renewal Awards. Recognizing that some projects such as those involving drug discovery and drug development require many years and hundreds of millions of dollars to complete, the NIH provides an opportunity for small business grantees to obtain a competing renewal of Phase II SBIR projects to address issues related to Federal regulatory processes (e.g., those involving the Food and Drug Administration approval process).

Commercialization Assistance Program. In order to assist Phase II SBIR awardees to advance projects from the research arena to the marketplace, the NIH offers a commercialization assistance program. The Program is designed to help some of the Nation's most promising small, life science companies develop their commercial business strategies, thereby providing them with exposure to and creating contacts within the life sciences industry and the investment community.

Other enhancement features of the NIH SBIR/STTR Programs include multiple submission dates and allowability of amended applications.

These improvements arise from and accommodate many of the needs of the small business research community. Those needs are varied and the challenges are great in trying to accommodate multiple industries, different technology sectors, and diverse product outcomes. For small businesses whose major focus is on technologies in areas such as instrumentation, health/medical education, and research tools, the phased SBIR program process is considered linear: Phase II = Phase III. However, for the

majority of the small businesses that we support whose major business focus is biotechnology, pharmaceuticals (e.g., drug discovery, drug development) and diagnostics, the phased SBIR program process is not linear, and unique challenges are presented. In these cases, a Phase I and Phase II award do not automatically translate to Phase III commercialization. Due to their early stage development, these projects are not candidates for capital investment, but are well suited for the SBIR program. Often, additional SBIR funding is needed to pursue lines of feasibility research related to the development of the product.

In conclusion, the NIH is very pleased with its involvement in the SBIR program and believes that flexibility is critical to the continued success of the program.

Thank you for the opportunity to appear before you today. I would be happy to answer any questions from the Committee.

Statement of Dr. Colien Hefferan, Administrator Cooperative State Research Education and Extension Service United States Department of Agriculture

Before

Committee on Small Business
Subcommittee on Workforce, Empowerment and Government Programs
United States House of Representatives
November 8, 2005

Good morning Madam Chairman. I am Dr. Colien Hefferan, Administrator of the Cooperative State Research, Education and Extension Service (CSREES) at the United States Department of Agriculture (USDA). The mission of CSREES is to advance knowledge for agriculture, the environment, human health and well-being, and communities through national program leadership and federal assistance. I appreciate the opportunity to come before the Committee today to discuss the Small Business Innovation Research Program administered by CSREES on behalf of all USDA agencies.

Today, I would like to provide an overview of the SBIR program within USDA by identifying the agencies that contribute funds to the program, the research topic areas that have been established and the method we use to determine grant recipients. I plan also to provide specific examples that illustrate how the SBIR program has successfully fostered agricultural innovation. Within USDA and CSREES we are very proud of this program that has supported over 1,600 research and development projects since its inception in 1982, allowing hundreds of small businesses to pursue innovative ideas and explore their technological potential.

Within USDA, the staff functions necessary to administer the SBIR program have been centralized in CSREES in order to provide the SBIR community effective, efficient and consistent service. These staff functions include solicitation, review and evaluation of proposals, award management and post award review. CSREES has well refined systems and procedures for administering grant programs such as SBIR due to our long history of managing grants to colleges and universities for extramural scientific research, education and extension activities.

Overall there are eight USDA agencies with sizeable research and development budgets that set aside 2.5% of their extramural research and development awards for the SBIR program.

These agencies are Agricultural Research Service (ARS), Animal Plant Health Inspection Service (APHIS), Cooperative State Research, Education and Extension Service (CSREES), Economic Research Service (ERS), Forest Service (FS), National Agricultural Statistics Service (NASS), Natural Resources Conservation Service (NRCS), and Foreign Agricultural Service (FAS). In fiscal year 2005 these agencies contributed over \$19.2 million to SBIR. Of the total USDA funding, approximately 80% is contributed by CSREES, about 12.5% is contributed by ARS and approximately 5% is contributed by the Forest Service.

The USDA-SBIR program administered by CSREES has two types of awards. The first is for Phase I feasibility studies that can be up to \$80,000 for eight months and the second is for Phase II research and development grants that can be up to \$300,000 for 24 months.

Approximately 90 Phase I feasibility grants and 35-40 Phase II research and development grants are awarded annually. Successful completion of a Phase I study is prerequisite to receipt of a Phase II grant. Of the applications received, 15 to 17% of the Phase I and 50 to 60% of the Phase II proposals have been funded each year.

The USDA-SBIR program administered by CSREES addresses twelve research topic areas that are aligned with the USDA strategic goals of enhancing economic opportunities for agricultural producers, increasing economic opportunities and improving the quality of life in Rural America, enhancing protection and safety of the Nation's agriculture and food supply, improving the Nation's nutrition and health and protecting and enhancing the Nation's natural resource base. These specific topic areas are Forests and Related Resources; Plant Production and Protection; Animal Production and Protection; Air, Water and Soils; Food Science and Nutrition; Rural and Community Development; Aquaculture; Industrial Applications; Marketing and Trade; Wildlife; Animal Waste Management; and the Small and Mid-Sized Farms topic area that was included for the first time for the fiscal year 2006 program.

Proposals are evaluated by a confidential peer review system similar to the one used by the National Research Initiative, the Department's flagship competitive research program. Review panels meet in Washington to review each proposal and the most meritorious proposals are recommended for funding. Panel members come from academic and government research laboratories. In addition, each proposal is sent to several ad-hoc reviewers who do not participate in the panel meeting but submit written reviews that are considered by the panel.

These ad-hoc reviewers are selected for their expertise relative to the specific proposal they are reviewing and come from academic and government laboratories all over the world.

An important aspect of the SBIR program is post-award management. Most of the effort is directed toward Phase II projects that have demonstrated technical feasibility in Phase I and are continuing their research and development. A commercialization assistance program is offered to new Phase II winners in which they work with a contractor who helps identify potential commercialization partners and markets, or new business opportunities. In addition, the USDA's SBIR National Program Leaders conduct many site visits and work closely with all of the Phase II projects to provide advice and guidance.

Since successful commercialization often takes several years or more after completion of a Phase II project, the USDA SBIR program maintains contact with past Phase II winners for many years in an effort to document those projects which achieve commercial success. Recently, the SBIR program has begun posting success stories on its website and I would like to introduce several of these as part of my written testimony. Surveys of past Phase II winners indicate that about 50 % of the Phase II projects ultimately realize success in the form of commercialization and sales.

I would like to briefly mention four examples of successful SBIR projects. The first is Embrex from Research Triangle Park, North Carolina. Chickens used to be vaccinated on the first day after hatching for a variety of diseases. USDA scientists showed that it was possible to vaccinate chickens by injecting the vaccine directly into the egg three days before hatching. To make this *in ovo* vaccination approach work, Embrex received SBIR support to develop an automatic egg injection machine. Their technology is capable of vaccinating over 30,000 eggs per hour and they now vaccinate over 90% of the 9 billion broiler chickens raised in this country every year. They also are vaccinating chickens in more than 30 foreign countries.

The second example is Sleepy Hollow Farm in Dalton, Georgia. This is a rural development project aimed at establishing an organic goldenseal production industry in rural northwest Georgia. Goldenseal is a popular medicinal herb valued for its anti-cancer, anti-diarrhea and anti-microbial activity. With SBIR support Sleepy Hollow Farm has established procedures for cultivating goldenseal under organic conditions. They have now recruited over

30 additional small farms to also raise goldenseal such that ultimately, the project is developing a new crop that can help improve the profitability of a number of small farms in the region.

The third company is The Nitrate Elimination Company in Lake Linden, in Michigan's Upper Peninsula. Nitrogen fertilizer is essential for plant production but excess amounts can contribute to elevated nitrate levels in crop tissues or drinking water that may cause health problems for humans and livestock. Accurate measurement of nitrate levels is therefore necessary. Traditionally nitrate has been measured by chemical tests that utilize cadmium, but cadmium can be very toxic and thus poses health and environmental concerns. The Nitrate Elimination Company has produced very sensitive test kits for nitrate that are based on the activity of the enzyme nitrate reductase. Compared to the traditional cadmium-based tests, this approach is more sensitive and far more environmentally friendly.

The last example comes from Fast Ditch, which is a Hispanic-owned small business located in Vallecitos, New Mexico. In the Southwest, irrigation is required to raise many crops, thus water is a critical issue. Many irrigation canals are unlined dirt ditches and when water is transported through these irrigation canals substantial amounts of water can be lost, especially in areas with sandy soils. Fast Ditch is working with the New Mexico State University Sustainable Agriculture Science Center in Alcalde, New Mexico to develop a system of interlocking plastic liners that fit in the irrigation ditches and greatly reduce water loss from the irrigation canals.

In closing, these are just several of the many examples we could cite to demonstrate how this program has encouraged business initiative and innovation in the agricultural sector of our economy. Since its inception, over 1600 innovators and entrepreneurs have received the resources they needed to examine the commercial feasibility of their ideas. Of this number, over 900 have received substantial assistance to further develop and commercialize these innovations. Based on previous success rates we expect half of these projects are likely to achieve some measure of commercial success. These successes are helping to keep America's agriculture strong and expand job opportunities in Rural America.

Thank you for the opportunity to appear before you today. I would be happy to answer any questions from the Committee.

Testimony Dr. Joe Hennessey Senior Advisor Office of Industrial Innovation National Science Foundation Before the

Subcommittee on Workforce, Empowerment and Government Programs of the Committee on Small Business of the United States House of Representatives November 8, 2005

Good morning, Madam Chair. My name is Joe Hennessey and I appreciate the opportunity to provide the committee with some background on NSF's Small Business Innovation Research program. I am Senior Advisor in the Office of Industrial Innovation at the National Science Foundation. In that role, I have oversight responsibility for the Small Business Innovation Research (SBIR) Program at the National Science Foundation (NSF). The SBIR program is located within the Office of Industrial Innovation (OII) reporting to the Assistant Director of the Engineering Directorate (ENG).

Background of SBIR

Let me begin by noting that SBIR was invented at NSF. As early as 1976, Roland Tibbetts of NSF initiated a new program for the support of the small business community with early-stage financial support for high-risk technologies with commercial promise. In 1982, based in part on the success of this program, Congress expanded the SBIR program to other agencies by passing the Small Business Innovation Research Development Act.

The Small Business Administration (SBA) is responsible for setting SBIR operational guidelines. All federal agencies submit annual reports to the SBA on SBIR budget calculation, list of awards made during the fiscal year and project abstracts. Agencies request clearance from the SBA on issues falling outside the guidelines. The SBA monitors all the Federal SBIR programs and issues reports and recommendations to Congress.

Phase I SBIR awards can be up to \$100,000 for up to 6 months and provide a small business with support to conduct research on a new technique or product. All Phase I grantees are eligible to apply for Phase II awards to conduct expanded research efforts to complete technical milestones as a pre-requisite for further commercialization. Phase II award size can be up to \$500,000 for a period of 2 years. The NSF SBIR program does not fund Phase III, the transformation of technology to a prototype and into the marketplace. NSF does, however, have a Phase IIB supplement program with awards up to \$500,000 to help bridge the research gap and to meet the needs of the third party investor.

Phase I proposals are reviewed for their technical merit by panels of experts form the academic and business communities. Phase II proposals are reviewed in the panel process for their technical merit by appropriate technical experts and for their commercial potential by experts from the business community. The funding recommendations from these review panels are advisory to the program managers who make the final funding recommendations.

The table below summarizes the results of the SBIR Phase I and Phase II program for 2002-2005.

NSF SBIR Proposal and Awards Results							
Year	Phase I Proposals	Awards	Phase II Proposals	Awards	Phase IIB Supplements	Total SBIR Funding	
2002	1477	277	148	66	39	\$78,000,000	
2003	2704	447	225	77	21	\$91,400,000	
2004	2450	236	308	127	22	\$95,400,000	
2005	1451	160	281	131	42	\$96,000.000	

SBIR at NSF

Since NSF is not a 'mission agency' with significant procurement needs, the focus of the NSF SBIR program from its inception has been on the commercialization of research. NSF historically has directed small businesses applying for SBIR grants to plan beyond Phase I to Phase II and Phase III all the way to commercialization. The NSF SBIR program participates in outreach conferences across the nation to educate the small business community on the goals of the SBIR program and emphasizes the need for commercialization focus when applying for a NSF SBIR Phase I grant.

All Phase I grantees are given an opportunity to compete for Phase II grants upon completion of their Phase I research. Phase II proposals require not only a research plan, but also a commercial plan. External assessments of the program by NSF SBIR Committee of Visitors (COV) noted that commercialization plans for Phase II proposals were not of the same quality of the technical plans. In 1999, SBIR introduced a Phase I training workshop "Doing Business with the NSF" in which the Phase I grantees are provided training in preparing commercialization plans as well as in other aspects of the Phase II submittal process.

In 2001 NSF initiated a contracted Commercialization Planning Assistance (CPA) program for all Phase I grantees using technical assistance set-aside funds. The success of the CPA program was confirmed by subsequent external assessments that analyzed Phase II proposals received in 2001-2003 as well as from the comments from the reviewers of the commercialization plans.

In 2001 SBIR began an Annual Phase II Grantees Conference that featured reviews of technical and commercial progress, networking among grantees and potential investors, and training sessions on intellectual property protection, licensing strategy and investment strategies. Both the small business and the investment communities have endorsed these conferences. They are continuing as an annual event.

The SBIR program is poised to offer further assistance to the small business community working within the language of the legislation of using SBIR set-aside funding for 'technical assistance'. In addition, it is seeking partnerships and other options to provide business assistance through the judicious use of its limited administrative resources.

Phase IIB

In 1998 NSF SBIR introduced a new supplemental program called Phase IIB as an incentive for partnering between the small business and investment communities. The NSF supplemental proposal is submitted while the company is conducting the Phase II research. With Phase II research underway the small business is better positioned to attract investors because most of the early stage research risk has already been addressed with federal funding.

Supplemental federal funding can be targeted at fine-tuning the research to address the needs of the investor, customer or strategic partner. The SBIR program requires that third party commitments be double the level of supplemental funding from NSF. The Phase IIB supplement was initiated to 'fill the gap' between the \$500,000 from an NSF Phase II grant and commercialization. The supplemental funding ranges between \$50,000 and \$500,000. Third party investors included both public and private sectors. For supplements over \$250,000, the small business must do a site visit to NSF with their investor. The Phase IIB program at NSF has been tremendously successful and has been showcased by the National Academies as a model to facilitate Phase III at its meeting in 2004.

The NSF SBIR participates in venture forums and other networking opportunities to publicize the NSF programs. The SBIR program officers have built personal relationships with members of the investment community to help make them aware of the opportunities with the small business community.

The NSF has also created 'SBIR MatchMaker' to encourage contact between investors and grantees. Members of the MatchMaker program are invited to Grantees Conferences to review technologies to see if it is potentially valuable to the investor. At the same meeting the industrial companies presented overviews of their own product requirements and identified technologies they are seeking to acquire. To stimulate interest by investors and strategic partners NSF has compiled a CD containing all Phase II awards over the span of the last five years and grouped by solicitation topics and subtopics representing a wide spectrum of technologies. The SBIR MatchMaker list of investors and strategic partners has grown to almost 50 potential third party partners and several 'matches' have been made.

NSF Unique Role

The NSF is a research-funding agency that underwrites the technical risk of new research before the private sector investment market is willing to get involved. Since NSF is not the ultimate customer of the innovation stimulated by the SBIR program, the NSF SBIR/STTR research topics are oriented to the external needs of the market place and the nation as a whole.

The solicitation topics fall into the following three broad areas:

- Investment Business Focused Technology: The NSF SBIR program fits the
 national innovation model in encouraging public-private innovation partnerships.
 Technologies of interest to private sector investment businesses include
 biotechnology, electronics technology and information-based technology.
- Industrial Market Driven Technology: The NSF SBIR program is in a strong
 position to orient its funding to create public-private partnership by identifying
 market driven technologies of interest to the large business that the small business
 community can respond such as advanced materials and manufacturing and
 chemical based technology.
- Technology in Response to National Needs: At times, there arise national needs
 that the private sector is not able to respond immediately to with the available
 technology base or the market is not considered large enough for the private
 sector to commit to long-term research.

Security-Based Technology (ST)

International terrorism triggered a heightened national need for security. Since NSF is already investing in the areas of Nanotechnology, Biotechnology and Information Technology, the SBIR program supports proposals that address security opportunities at the intersection of one or more of these technologies.

Manufacturing Innovation (MI)

In response to Executive Order 13329 requiring all federal agencies with SBIR programs to emphasize manufacturing research as a way to spur innovations to reverse erosion of the manufacturing base, the NSF SBIR is positioned to stimulate innovation in other technologies in support of national needs.

In addition, small business innovations provide tools to further advanced research and education by academia. Some examples include robust remote sensors for geosciences, enhanced data gathering by atomic force microscopes for materials science and biosciences and education software for bringing science to elementary schools.

SBIR Role in Workforce Development

The NSF has a very successful supplemental program - Research Experience for Undergraduates (REU) - to attract undergraduate students to careers in research. This was recently expanded to include K-12 teachers through the Research Experience of Teachers (RET) supplemented program. The SBIR/STTR grantees perceive these programs as very attractive supplements and are glad to offer students and teachers an opportunity to experience the small business research environment. In addition, the small business has an opportunity to attract and hire students as their businesses grow. Recognizing that the small business is the major employer of scientists and engineers in the U.S., these supplemental programs play a critical role in training the future workforce of scientists and engineers for their careers.

The Small Business Innovation Development Act stipulates - 'Foster and encourage participation by minorities and disadvantaged persons in technological innovation'. Currently participation by minority- and woman-owned businesses in the NSF SBIR/STTR program averages 20% overall with a ratio of 2:1 between minorities and women. There is a need to be proactive to expose qualified minority and women owned businesses to the competitive opportunities in the SBIR program.

In 2005 the SBIR program initiated a contracted field representative position to give special priority to mentoring minority and other small businesses that are classically underrepresented in the SBIR program and thereby increasing their skills to compete on a national level in the small business programs offered by the Federal government.

In 2004, SBIR initiated a partnership (Phase IIA) with the Centers for Research Excellence in Science and Technology (CREST) program in the NSF Education and Human Resources (EHR) Directorate to offer supplements to SBIR/STTR Phase II grants to partner with the predominantly minority CREST academic research institutions. The goal of this pilot supplemental program is to encourage researchers from CREST institutions to conduct basic research that has a direct consequence to the SBIR/STTR grantee. The total amount of the supplemental Phase IIA is up to \$150,000 with at least 70% available as sub-award to the partnered CREST institution.

Historically the SBIR program has collaborated with the Experimental Program to Stimulate Competitive Research (EPSCoR) to co-fund SBIR awards to small businesses in EPSCoR designated states. This program has had a positive impact on that community. The EPSCoR program also supports SBIR outreach in those areas.

Building Partnerships with Academia

The SBIR program has a strong relationship university community because of the NSF role in support of research. Many of the companies are faculty-founded small businesses

or university-led partnerships. A significant number of SBIR grantees have sub-contracts, consulting agreements and other relationships with universities and their facility. Faculty members are generally eager to serve as reviewers and express interest in more participation in the SBIR/STTR program. In fact, some expressed interest in knowing and following the progress of the small business grantees that they had recommended for awards.

The NSF SBIR program believes it is in a unique position to encourage partnerships between established small businesses and academia to transform discovery into innovation and actively support emerging small businesses rooted in university-based technology towards commercialization.

SBIR Program Management

The NSF SBIR program is committed to award all Phase I and Phase II grants within six (6) months of the posted solicitation deadline as mandated by SBIR legislation and consistent with the NSF dwell time requirements. The program is staffed with a team of program officers with strong technical backgrounds in the technical areas supported by the program and with business experience in large and small organizations. The SBIR program officers generate the topics, review the proposals and manage the awards. This "one-stop" point of contact for the small business community is somewhat unique in the SBIR program. To support the very high volume of proposals, a flexible contract support staffing is used in response to the cyclical proposal processing demand

The SBIR program officers include personnel with deep domain knowledge and strong technical backgrounds representing technologies of interest to the investment business and industrial market segments. These program officers have many years of industrial experience, either in small or large businesses where they either founded the technology company and/or had technical and management responsibilities. In order to create time for program managers to create value for the small business community for award portfolio management and mentoring of grantees, technology assistants were recently hired as additional contract staff to assist the program officers. This experiment is ongoing and has the potential to lower the program officers' workload in the review and decision process this enhance the award management and mentoring function of program management.

SBIR Outreach

Since its inception in the early '80s, the NSF SBIR program has taken a leadership role in organizing national conferences to attract small businesses to participate in the SBIR programs. Currently, all eleven (11) federal agencies that implement the SBIR program participate at these NSF-sponsored Conferences. In order to stimulate small businesses in the rural states, conference sites are selected such that at least one outreach national conference in a year occurs in an EPSCoR state.

The NSF SBIR External Advisory Committee recognizes the federal leadership achievement of NSF in support of the small business community outreach and is encouraging SBIR to move on to the next important role of providing mentorship and assistance to the small business grantees base. The NSF SBIR will seek another agency or organization to take over the national conference planning starting FY 2007, so that the NSF SBIR can channel its resources to the mentorship of small business grantees. The individual states are increasingly proactive in attempting to bring more federal SBIR dollars into their regions as part of economic development in their region. The NSF SBIR supports and participates in States' efforts subject to the limited availability of time and travel funds. Invitational travel for outreach from the EPSCoR states is often supported by the NSF EPSCoR program.

Measuring Success

Assessment of the outcome of awards in the SBIR program is essential to determining the value created by the program. While anecdotal information has been broadly collected, the systematic collection of commercialization results on individual awards has been problematic to collect and systematically analyze. The NSF SBIR Phase II awardees are asked to provide, on an intermittent basis, a Commercialization Report after the conclusion of the award. The NSF SBIR has developed a new telephone interview process (endorsed by the SBIR External Advisory Committee) to gather this information on the 3rd, 5th and 8th anniversary of the end of the award. The telephone interview is part of the expanded awards management responsibilities of the program manager. The information on the company, the current status of commercialization, the products and/or services developed, why commercialization may have failed, intellectual property situation, key strategic and /or investor relationships, and employment statistics will be collected for a data base for subsequent analysis and regular reports.

Examples of SBIR Awards Success

Let me provide for the record a few of the many success stories that have come from the NSF SBIR program.

CardioMag Imaging (CMI) has developed a medical device ("Magnetocardiograph") based on Superconducting Quantum Interference Devices (SQUIDs) that measures magnetic fields emitted by the electrophysiological activity of the human heart. It can be used in regular, magnetically unshielded hospital rooms for early non-invasive diagnosis of heart disease such as ischemia in patients with Acute Coronary Syndrome (ACS). The device is currently being tested in the emergency rooms of six clinics in the United States and Europe.

Real-Time Analyzers has developed an anthrax detection system designed to help protect postal workers and the public at large. The system is designed to examine incoming or suspect mail. The initial sampling station is equipped with a perforated surface over a downdraft vent. These sampling stations are connected to a vacuum system that entrains the spores in air, carries them to a cyclone that separates the spores and

delivers them to a filter-tape for collection and measurement by Raman analyzer. The system is designed to detect the presence of anthrax while preventing false positives, which causes significant mailing disruption and expense Real-Time Analyzers is partnering with ID Mail Systems, a major manufacturer of mail handling equipment, to commercialize their anthrax detection system.

Luna Innovations has developed dramatically improved contrast agents based on carbon nanospheres for magnetic resonance imaging (MRI) diagnostics. There are many instances where an MRI scan is not prescribed because no contrast agent exists. In addition, improved contrast agents increase diagnosis accuracy and reduce treatment cost. Their researchers discovered a new class of molecules-- endohedral metallofullerenes called Trimetaspheres that allows three metal ions to be encapsulated within a fullerene structure. Trimetaspheres have been shown to be more than 50 times better in terms of sensitivity than traditional contrast agents. They are also safer-- because the metal ions cannot escape the carbon cage-- and they provide an excellent platform for cell targeting. For example, within the brain, Trimetaspheres can pass the blood-brain barrier and are small enough to fit inside the smaller regions of blood vessels. These contrast agents dramatically improve patient care and lower medical costs by improving existing MRI diagnostics and providing new contrast agents that allow diagnoses in cases where there is no current method. Luna Innovations has invested significantly into a Trimetasphere production facility. The technology developed in this program is being applied in current MRI measurements and satisfies requirements for future high field strength MRI instruments. The company is partnering with pharmaceutical companies to bring these new contrast agents to an expanding market.

Mendel Biotechnology, Inc has optimized their technology for engineering broadspectrum disease resistance in crop plants. Protection of crops against pathogens is one of
the most significant unmet needs in agriculture. Despite billions of dollars spent on
fungicides and other crop protection chemicals every year, large losses still occur. These
researchers have established that over expression of the transcription factors AtERF1
confers resistance against several fungal pathogens. During this program they have
characterized the crop homologs, demonstrated the function in tomatoes, and have
optimized the technology by targeting expression to different tissues. In addition, they
have also broadened the spectrum of resistance through combinatorial expression with
other transcription factors and have improved the control of the transmission factors by
creating derivatives with enhanced activity. Mendel Biotechnology is continuing with the
commercialization of their "DiseaseGard" technology based on AtERF1 transcription
factors that will enable growers to increase productivity of important agricultural crops
by reducing losses due to pathogens and by decreasing expenditures for fungicides by
using crops with enhanced resistance to a broad spectrum of pathogens.

AnthroTronix, Inc has developed an interactive robotic system to facilitate receptive and expressive language development of children with disabilities. This child-friendly robot is controlled by various interfaces adapted to individual needs, regardless of physical limitations. The child controls the robot via gestures and voice activation. Gestures include reaching for a button, operating a joystick, or activating wearable

sensors through body movement. The child can play and record sound and movement commands and interact with the robot in the context of programmed games. The robot allows the child to interact with its environment. The controlling software can be updated so that the robot continues to hold the child's interest and imagination over time. This robotic technology provides interventional activities, motivation and reinforcement for learning and speech/language therapy. The number of children with speech and language impairments is higher than any other disability. This robotic system provides therapists with an effective tool that supports an approach that integrates speech/language development with children's educational and social development, such as communication and interpersonal skills. This innovation enables therapists to provide increased motivation and education of children with disabilities while performing therapeutic functions.

Big Horn Valve, Inc has developed an emissions-free valve for the petroleum refining and chemical processing industries that utilizes rotary magnetic coupling with manual and pneumatic operation. This new valve provides significant internal seal improvement with reduced friction for extended life and improved flow efficiency and controllability. Failsafe operation combined with modularization for assembly and service are very important to the petrochemical refining and chemical industries where fugitive emissions from leaky valves have become the most critical environmental regulatory issue and where the current valve designs are deemed to be inadequate. They are currently working with strategic partners in the chemical processing industries to bring the technology to market.

NanoScale Materials, Inc. has developed the toxic-chemical cleaner known as FAST-ACT composed of magnesium, titanium and oxygen. This new family of powders packs a punch--crammed onto each tiny grain is an enormous surface area and a seemingly limitless thirst for hazardous substances. When sprayed from a canister or spread over a spill, the material attaches to and rapidly breaks apart the material into a harmless state. Kansas State University chemist Kenneth Klabunde was the first to devise the nanoengineering techniques that led to the development of FAST-ACT with support from NSF. The company was founded to produce this new family of substances. The SBIR program supported created the manufacturing processes for commercial-scale production.

Imago Scientific Instruments Corp. is developing specimen preparation and analysis methods that will enable the LEAP® (Local Electrode Atom Probe) microscope to be used to determine the 3-D structure and the elemental composition of biological and organic molecules on nano-biotechnology devices such as DNA chips, biosensors, medical implants etc. Instrument sales incorporating the Phase II technology are in the early stages. The company is collaborations with and / or providing analytical services to Structural Biology / Proteomics/ Medical Devices companies to broaden their market.

Areas for Improvement

Over the last 7-8 years the SBIR program has significantly increased the emphasis on commercialization planning and private sector commercialization success. Investments in education in business planning and the techniques secure investment capital should pay significant dividends for increased return on the Federal investments in the SBIR program. Given this emphasis it seems reasonable to evaluate the provisions of the SBIR reauthorization legislation for discretionary technical assistance to determine if they are adequate.

The Small Business Administration is currently coordinating with the Office and Management and Budget on an assessment of the effectiveness, management, and performance measurement of the SBIR/STTR programs at the Department of Defense, NASA, the Department of Energy, the National Institutes of Health, and NSF. We expect to use the findings of that assessment to address any shortcomings in NSF's program, and primarily to develop robust outcome measures.

The NSF SBIR program is also looking forward to the results of the current study by the National Academies of the whole SBIR program that should highlight other areas for improvement.

Madam Chair, this concludes my testimony. On behalf of the National Science Foundation, the SBIR program and our awardees, I want to thank you for this opportunity to highlight a program that provides small businesses with an opportunity to keep America on the forefront of innovation. I would be pleased to provide any additional information that would be useful to you.

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